ALEXANDER G. CALFO (SBN 152891)
acalfo@kslaw.com
JULIA E. ROMANO (SBN 260857)
jromano@kslaw.com
KING & SPALDING LLP
633 West Fifth Street
Suite 1600
Los Angeles, CA 90071
Telephone: +1 213 443 4355
Facsimile: +1 213 443 4310

SHANNON E. BEAMER, SBN 331289
sebeamer@venable.com
VENABLE LLP
2049 Century Park East, Suite 2300
Los Angeles, CA 90067
Telephone: +1 310 229 9682
Facsimile: +1 310 229 9901

Attorneys for Defendants
MERCK & CO., INC.; MERCK SHARP & DOHME CORP.[1]; ORGANON & CO.; and ORGANON LLC

UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF CALIFORNIA

SHERRY WALLACE, an individual,

Plaintiff,

vs.

MERCK & CO., INC., a New Jersey Corporation; MERCK SHARP & DOHME CORP., a New Jersey Corporation; ORGANON & CO., a Delaware Corporation; ORGANON LLC, a Delaware Limited Liability Company; and DOES 1-10, Inclusive,

Defendants.

Case No.

DECLARATION OF J. ROMANO IN SUPPORT OF NOTICE OF REMOVAL AND REQUEST FOR JUDICIAL NOTICE

[Merced County Superior Court Case No. 22CV-00737]

Action Filed: March 4, 2022
Action Removed: May 20, 2022
Trial Date: None Set

[1] Merck Sharp & Dohme Corp. is now known as Merck Sharp & Dohme LLC.

I, Julia E. Romano, hereby declare and state as follows:

1. I am an attorney licensed to practice law in California and a Partner at King & Spalding, LLP, counsel of record for defendants MERCK & CO., MERCK SHARP & DOHME CORP., ORGANON & CO., and ORGANON LLC (collectively, "Defendants"). I have personal knowledge of the matters stated below and, if called upon, could and would testify competently thereto.

2. This declaration is submitted in support of Defendants' Notice of Removal and Removal of Action and Request for Judicial Notice in Support of Defendants' Notice of Removal and Removal.

3. Attached hereto as **Exhibit 1** is a true and correct copy of the Complaint, filed in the Superior Court of the State of California, County of Merced on or about March 4, 2022, entitled *Sherry Wallace v. Merck & Co., et al.* Merced County Superior Court Case No. 22CV-00737, along with the Summons and Civil Case Cover Sheet.

4. On March 7, 2022, our co-counsel Venable LLP ("Venable") downloaded a PDF of the New Jersey Secretary of State's Entity Details for **Merck & Co., Inc.** Venable found this form by: (1) typing the following URL address into the New Jersey Secretary of State Business Search website into the search bar: https://www.njportal.com/DOR/businessrecords/Default.aspx; (2) clicking the link for "Business Entity Standing Certificates;" (3) clicking "Business Name;" (4) entering the company name "Merck & Co., Inc.," into the box labeled "Business Name;" (5) selecting the button labeled "Continue;" (6) selecting the first box under the heading "Short Form;" (7) adding the document to the cart; (8) purchasing the document; and (9) downloading the document using an access code.

5. Attached hereto as **Exhibit 2** is a true and correct copy of the New Jersey Secretary of State's Business Entity Short Form Standing Certificate for **Merck & Co., Inc.**, that Venable downloaded using the foregoing process.

6. On March 7, 2022, Venable downloaded a PDF of the New Jersey Secretary of State's Status Report for **Merck & Co., Inc.** Venable found this form by: (1) typing the following URL address into the New Jersey Secretary of State Business Search website into the search bar:

https://www.njportal.com/DOR/businessrecords/Default.aspx; (2) clicking the link for "Business Entity Status Reports;" (3) clicking "Business Name;" (4) entering the company name "Merck & Co., Inc.," into the box labeled "Business Name;" (5) selecting the button labeled "Continue;" (6) selecting the first box under the heading "Order Status Report;" (7) adding to cart; (8) purchasing the document; and (9) downloading the document using an access code.

7. Attached hereto as **Exhibit 3** is a true and correct copy of the New Jersey Secretary of State's Status Report for **Merck & Co., Inc.**, that Venable downloaded using the foregoing process.

8. On May 18, 2022, I downloaded an electronic copy of the California Secretary of State's Statement of Information for **Merck Sharp & Dohme Corp.** by: (1) going to the California Secretary of State business search website: https://bizfileonline.sos.ca.gov/search/business; (2) entering the company name "Merck Sharp & Dohme Corp." into the search box and clicking "search;" (3) selecting the second link displayed, labeled "Merck Sharp & Dohme Corp. (200917);" (4) clicking "View History;" (5) selecting "Statement of Information – 12/20/2021;" and (6) selecting "Download."

9. Attached hereto as **Exhibit 4** is a true and correct copy of the California Secretary of State's Statement of Information for **Merck Sharp & Dohme Corp.**, filed on December 20, 2021, that I accessed using the foregoing process.

10. Effective May 1, 2022, Merck Sharp & Dohme Corp. merged into Merck Sharp & Dohme LLC.

11. On May 19, 2022, I downloaded a PDF of the New Jersey Secretary of State's Entity Details for **Merck Sharp & Dohme LLC**. I found this form by: (1) typing the following URL address into the New Jersey Secretary of State Business Search website into the search bar: https://www.njportal.com/DOR/businessrecords/Default.aspx; (2) clicking the link for "Business Entity Standing Certificates;" (3) clicking "Business Name;" (4) entering the company name "Merck Sharp & Dohme LLC," into the box labeled "Business Name;" (5) selecting the button labeled "Continue;" (6) selecting the first box under the heading "Short Form;" (7) adding the document to the cart; (8) purchasing the document; and (9) downloading the document.

12. Attached hereto as **Exhibit 5** is a true and correct copy of the New Jersey Secretary of State's Business Entity Short Form Standing Certificate for **Merck Sharp & Dohme LLC** that I downloaded using the foregoing process.

13. On May 19, 2022, I downloaded a PDF of the New Jersey Secretary of State's Status Report for **Merck Sharp & Dohme LLC**. I found this form by: (1) typing the following URL address into the New Jersey Secretary of State Business Search website into the search bar: https://www.njportal.com/DOR/businessrecords/Default.aspx; (2) clicking the link for "Business Entity Status Reports;" (3) clicking "Business Name;" (4) entering the company name "Merck Sharp & Dohme LLC" into the box labeled "Business Name;" (5) selecting the button labeled "Continue;" (6) selecting the first box under the heading "Order Status Report;" (7) adding to cart; (8) purchasing the document; and (9) downloading the document.

14. Attached hereto as **Exhibit 6** is a true and correct copy of the New Jersey Secretary of State's Status Report for **Merck Sharp & Dohme LLC** that I downloaded using the foregoing process.

15. On March 7, 2022, Venable requested a copy of the Delaware Division of Corporations Short Form Standing Certificate for **Organon & Co**. Venable found this form by: (1) typing the following URL address into the Delaware Division of Corporations website into the search bar: https://icis.corp.delaware.gov/ecorp2/services/e-filing; (2) clicking the link for "certificate request;" (3) clicking "Document Upload;" (4) entering certification request information for the company name "Organon & Co.," into the box labeled "Corporation Name;" (5) selecting the method of return "Fed Ex," (6) selecting the button labeled "Continue," (7) purchasing the document; and (8) receiving the document via Fed Ex delivery on March 9, 2022.

16. Attached hereto as **Exhibit 7** is a true and correct copy of the Delaware Division of Corporations Short Form Standing Certificate for **Organon & Co.**, that Venable received via Fed Ex using the foregoing process.

17. On March 7, 2022, Venable downloaded a PDF of the New Jersey Secretary of State's Entity Details for **Organon & Co**. Venable found this form by: (1) typing the following URL address into the New Jersey Secretary of State Business Search website into the search bar:

https://www.njportal.com/DOR/businessrecords/Default.aspx; (2) clicking the link for "Business Entity Standing Certificates;" (3) clicking "Business Name;" (4) entering the company name "Organon & Co.," into the box labeled "Business Name;" (5) selecting the button labeled "Continue;" (6) selecting the first box under the heading "Short Form;" (7) adding the document to the cart; (8) purchasing the document; and (9) downloading the document using an access code.

18. Attached hereto as **Exhibit 8** is a true and correct copy of the New Jersey Secretary of State's Business Entity Short Form Standing Certificate for **Organon & Co.**, that Venable downloaded using the foregoing process.

19. On March 7, 2022, Venable requested a copy of the Delaware Division of Corporations Short Form Standing Certificate for **Organon LLC**. Venable found this form by: (1) typing the following URL address into the Delaware Division of Corporations website into the search bar: https://icis.corp.delaware.gov/ecorp2/services/e-filing; (2) clicking the link for "certificate request;" (3) clicking "Document Upload;" (4) entering certification request information for the company name "Organon LLC," into the box labeled "Corporation Name;" (5) selecting the method of Return "Fed Ex," (6) selecting the button labeled "Continue," (7) purchasing the document; and (8) receiving the document via Fed Ex delivery on March 9, 2022.

20. Attached hereto as **Exhibit 9** is a true and correct copy of the Delaware Division of Corporations Short Form Standing Certificate for **Organon LLC**, that Venable received via Fed Ex using the foregoing process.

21. On March 7, 2022, Venable downloaded a PDF of the New Jersey Secretary of State's Entity Details for **Organon LLC**. Venable found this form by: (1) typing the following URL address into the New Jersey Secretary of State Business Search website into the search bar: https://www.njportal.com/DOR/businessrecords/Default.aspx; (2) clicking the link for "Business Entity Standing Certificates;" (3) clicking "Business Name;" (4) entering the company name "Organon LLC," into the box labeled "Business Name;" (5) selecting the button labeled "Continue;" (6) selecting the first box under the heading "Short Form;" (7) adding to cart; (8) purchasing the document; and (9) downloading the document using an access code.

22. Attached hereto as **Exhibit 10** is a true and correct copy of the New Jersey Secretary of State's Business Entity Short Form Standing Certificate for **Organon LLC**, that Venable downloaded using the foregoing process.

23. On May 18, 2022, I downloaded an electronic copy of the California Secretary of State's Statement of Information for **Organon LLC** by: (1) going to the California Secretary of State business search website: https://bizfileonline.sos.ca.gov/search/business; (2) entering the company name "Organon LLC." into the search box and clicking "search;" (3) selecting the second link displayed, labeled "ORGANON LLC (202017610765);" (4) clicking "View History;" (5) selecting "Statement of Information – 5/17/2021;" and (6) selecting "Download."

24. Attached hereto as **Exhibit 11** is a true and correct copy of the California Secretary of State's Statement of Information for **Organon LLC**, filed on May 17, 2021, that I accessed using the foregoing process.

I declare under penalty of perjury under the laws of the United States, that the foregoing is true and correct.

Executed on May 20, 2022, at Los Angeles, California.

/s/ Julia E. Romano

Julia E. Romano

EXHIBIT 1

CT Corporation

Service of Process Transmittal

04/20/2022
CT Log Number 541437772

TO: Office of the Corporate Secretary
Organon & Co.
30 HUDSON ST FL 33
JERSEY CITY, NJ 07302-4600

RE: **Process Served in California**

FOR: Organon & Co. (Domestic State: DE)

ENCLOSED ARE COPIES OF LEGAL PROCESS RECEIVED BY THE STATUTORY AGENT OF THE ABOVE COMPANY AS FOLLOWS:

TITLE OF ACTION:	Re: SHERRY WALLACE,an individual // To: Organon & Co.
DOCUMENT(S) SERVED:	--
COURT/AGENCY:	None Specified Case # 22CV00737
NATURE OF ACTION:	Product Liability Litigation - Breach of Warranty
ON WHOM PROCESS WAS SERVED:	C T Corporation System, GLENDALE, CA
DATE AND HOUR OF SERVICE:	By Process Server on 04/20/2022 at 01:03
JURISDICTION SERVED :	California
APPEARANCE OR ANSWER DUE:	None Specified
ATTORNEY(S) / SENDER(S):	None Specified
ACTION ITEMS:	SOP Papers with Transmittal, via UPS Next Day Air Image SOP Email Notification, Office of the Corporate Secretary secretaryoffice@organon.com Email Notification, Lori Holmes lori.holmes@organon.com Email Notification, Tim Garcia timothy.garcia@organon.com Email Notification, Cherie Macciachera cherie.macciachera@organon.com
REGISTERED AGENT ADDRESS:	C T Corporation System 330 N BRAND BLVD STE 700 GLENDALE, CA 91203 866-401-8252 EastTeam2@wolterskluwer.com

Wolters Kluwer

PROCESS SERVER DELIVERY DETAILS

Date: Wed, Apr 20, 2022
Server Name: Douglas Forrest

Entity Served	ORGANON & CO.
Case Number	22cv00737
Jurisdiction	CA

Inserts		

SUM-100

SUMMONS
(CITACION JUDICIAL)

NOTICE TO DEFENDANT:
(AVISO AL DEMANDADO):
MERCK & CO., INC., a New Jersey Corporation; MERCK SHARP & DOHME CORP. a New Jersey Corporation; ORGANON & CO., a Delaware Corporation; ORGANON LLC, a Delaware Limited Liability Company; and DOES 1-10, Inclusive,

YOU ARE BEING SUED BY PLAINTIFF:
(LO ESTÁ DEMANDANDO EL DEMANDANTE):
SHERRY WALLACE, an individual,

FOR COURT USE ONLY
(SOLO PARA USO DE LA CORTE)

ELECTRONICALLY FILED
Merced Superior Court
3/4/2022 10:08 AM
Amanda Toste
Clerk of the Superior Court
By: Tawn Saephanh, Deputy

NOTICE! You have been sued. The court may decide against you without your being heard unless you respond within 30 days. Read the information below.

You have 30 CALENDAR DAYS after this summons and legal papers are served on you to file a written response at this court and have a copy served on the plaintiff. A letter or phone call will not protect you. Your written response must be in proper legal form if you want the court to hear your case. There may be a court form that you can use for your response. You can find these court forms and more information at the California Courts Online Self-Help Center (*www.courtinfo.ca.gov/selfhelp*), your county law library, or the courthouse nearest you. If you cannot pay the filing fee, ask the court clerk for a fee waiver form. If you do not file your response on time, you may lose the case by default, and your wages, money, and property may be taken without further warning from the court.

There are other legal requirements. You may want to call an attorney right away. If you do not know an attorney, you may want to call an attorney referral service. If you cannot afford an attorney, you may be eligible for free legal services from a nonprofit legal services program. You can locate these nonprofit groups at the California Legal Services Web site (*www.lawhelpcalifornia.org*), the California Courts Online Self-Help Center (*www.courtinfo.ca.gov/selfhelp*), or by contacting your local court or county bar association. **NOTE:** The court has a statutory lien for waived fees and costs on any settlement or arbitration award of $10,000 or more in a civil case. The court's lien must be paid before the court will dismiss the case.
¡AVISO! *Lo han demandado. Si no responde dentro de 30 días, la corte puede decidir en su contra sin escuchar su versión. Lea la información a continuación.*

Tiene 30 DÍAS DE CALENDARIO después de que le entreguen esta citación y papeles legales para presentar una respuesta por escrito en esta corte y hacer que se entregue una copia al demandante. Una carta o una llamada telefónica no lo protegen. Su respuesta por escrito tiene que estar en formato legal correcto si desea que procesen su caso en la corte. Es posible que haya un formulario que usted pueda usar para su respuesta. Puede encontrar estos formularios de la corte y más información en el Centro de Ayuda de las Cortes de California (www.sucorte.ca.gov), en la biblioteca de leyes de su condado o en la corte que le quede más cerca. Si no puede pagar la cuota de presentación, pida al secretario de la corte que le dé un formulario de exención de pago de cuotas. Si no presenta su respuesta a tiempo, puede perder el caso por incumplimiento y la corte le podrá quitar su sueldo, dinero y bienes sin más advertencia.

Hay otros requisitos legales. Es recomendable que llame a un abogado inmediatamente. Si no conoce a un abogado, puede llamar a un servicio de remisión a abogados. Si no puede pagar a un abogado, es posible que cumpla con los requisitos para obtener servicios legales gratuitos de un programa de servicios legales sin fines de lucro. Puede encontrar estos grupos sin fines de lucro en el sitio web de California Legal Services, (www.lawhelpcalifornia.org), en el Centro de Ayuda de las Cortes de California, (www.sucorte.ca.gov) o poniéndose en contacto con la corte o el colegio de abogados locales. AVISO: Por ley, la corte tiene derecho a reclamar las cuotas y los costos exentos por imponer un gravamen sobre cualquier recuperación de $10,000 ó más de valor recibida mediante un acuerdo o una concesión de arbitraje en un caso de derecho civil. Tiene que pagar el gravamen de la corte antes de que la corte pueda desechar el caso.

The name and address of the court is:
(El nombre y dirección de la corte es): Merced Superior Court
627 W 21st Street, Merced, CA 9540

Old Merced Courthouse

CASE NUMBER:
(Número del Caso): 22CV-00737

The name, address, and telephone number of plaintiff's attorney, or plaintiff without an attorney, is:
(El nombre, la dirección y el número de teléfono del abogado del demandante, o del demandante que no tiene abogado, es):
Shehnaz M. Bhujwala, SBN# 223484, Boucher LLP, 21600 Oxnard St., Suite 600, Woodland Hills, CA 91367
(818) 340-5400

DATE: 3/4/2022 10:08 AM *(Fecha)* Amanda Toste Clerk, by *(Secretario)* _____ , Deputy *(Adjunto)*

(For proof of service of this summons, use Proof of Service of Summons *(form POS-010).)*
(Para prueba de entrega de esta citatión use el formulario Proof of Service of Summons, *(POS-010)).*

[SEAL]

NOTICE TO THE PERSON SERVED: You are served
1. ☐ as an individual defendant.
2. ☐ as the person sued under the fictitious name of *(specify):*
3. ☒ on behalf of *(specify):* Organon & Co
   under: ☒ CCP 416.10 (corporation) ☐ CCP 416.60 (minor)
   ☐ CCP 416.20 (defunct corporation) ☐ CCP 416.70 (conservatee)
   ☐ CCP 416.40 (association or partnership) ☐ CCP 416.90 (authorized person)
   ☐ other *(specify):*
4. ☒ by personal delivery on *(date):*

Kevin P. Roddy, CA State Bar No. 128283
kroddy@wilentz.com
WILENTZ, GOLDMAN & SPITZER, P.A.
90 Woodbridge Center Drive, Suite 900
Woodbridge, New Jersey 07095
Tel: (732) 855-6402

Kimberly Beck, *Pro Hac Vice*
kim@becklawcenter.com
BECK LAW CENTER
201 E. 5th Street, Suite 1900
Cincinnati, Ohio
Tel: (888) 434-2912

Shehnaz M. Bhujwala, CA State Bar No. 223484
bhujwala@boucher.la
BOUCHER LLP
21600 Oxnard Street, Suite 600
Woodland Hills, California 91367-4903
Tel: (818) 340-5400
Fax: (818) 340-5401

Attorneys for Plaintiff

SUPERIOR COURT OF THE STATE OF CALIFORNIA

COUNTY OF MERCED

SHERRY WALLACE, an individual,

Plaintiff,

v.

MERCK & CO., INC., a New Jersey Corporation; MERCK SHARP & DOHME CORP. a New Jersey Corporation; ORGANON & CO., a Delaware Corporation; ORGANON LLC, a Delaware Limited Liability Company; and DOES 1-10, Inclusive,

Defendants.

Case No. 22CV-00737

COMPLAINT FOR DAMAGES AND DEMAND FOR JURY TRIAL

1. **STRICT LIABILITY - DESIGN DEFECT**
2. **STRICT LIABILITY - FAILURE TO WARN**
3. **NEGLIGENCE**
4. **NEGLIGENT MISREPRESENTATION**
5. **BREACH OF EXPRESS WARRANTY**
6. **BREACH OF IMPLIED WARRANTY**

Plaintiff SHERRY WALLACE, an individual, (hereinafter "Plaintiff"), alleges the following facts and claims for relief against Defendants MERCK & CO., INC. a New Jersey Corporation, MERCK SHARP & DOHME CORP., a New Jersey Corporation, (collectively referred to as "Merck Defendants" or "Merck"), Organon & Co., a Delaware Corporation, and Organon LLC, a Delaware Limited Liability Company (collectively referred to as "Organon Defendants" or "Organon") and DOES 1 through 10, inclusive, (all collectively referred to herein as "Defendants") and requests a trial by jury of all issues and causes of action so triable:

INTRODUCTION

1. SHERRY WALLACE has developed neuropsychiatric injuries as a result of ingesting Defendants' prescription pharmaceutical product, Singulair®, indicated for: a) prophylactic and chronic treatment of asthma; b) acute prevention of exercise- induced bronchoconstriction (EIB); and c) relief of symptoms of allergic rhinitis.

2. Merck Defendants knew or should have known of the risks of neuropsychiatric injuries prior to the time they began selling Singulair® in 1998. In 1996, Defendant Merck & Co., Inc. filed a patent application for montelukast, the active ingredient in Singulair®, acknowledging montelukast's possible effects on cerebral spasm. Further, montelukast has been tested extensively starting prior to 1998, and continuing through today. Many of these studies have demonstrated a correlation—and some show causation—between Singulair® usage andthe development of neuropsychiatric events. Merck Defendants have ignored these studies.

3. Originally, the Singulair® label contained no warnings regarding neuropsychiatric events. Over the past 24 years Merck Defendants have slowly and belatedly added grossly insufficient warnings regarding neuropsychiatric events to the product label. Finally,on March 4, 2020, the Food & Drug Administration (FDA) required Merck Defendants to add a BlackBox Warning, the strongest type of warning, to Singulair®'s label, regarding neuropsychiatric events. FDA also required a new Medication Guide.

4. The new Black Box warning provides "serious neuropsychiatric events have been reported in patients taking Singulair®." These include:

agitation, aggressive behavior or hostility, anxiousness, depression, disorientation,

> disturbance in attention, dream abnormalities, dysphagia (stuttering), hallucinations, insomnia, irritability, memory impairment,obsessive-compulsive symptoms, restlessness, somnambulism, suicidal thoughts and behavior (including suicide), tic, and tremor…
>
> Psychiatric disorders: agitation including aggressive behavior or hostility, anxiousness, depression, disorientation, dream abnormalities, hallucinations, insomnia, irritability, restlessness, somnambulism, suicidal thinking andbehavior (including suicide), tremor *[see Warnings and Precautions (5.4)]*.[1]

The new warning goes on to state "the benefits of Singulair® may not outweigh the risks…".

5. Merck Defendants also modified the drug labeling Section 5.1 to disclose some neuropsychiatric events that were reported after Singulair® discontinuation as well as acknowledge montelukast, the active ingredient in Singulair®, distribution into the brain in rats. In addition, Merck Defendants modified Section 12.3 to remove the word 'minimal' from the description of montelukast distribution into the brain.

6. In its March 4, 2020, press release FDA noted that "many patients and health care professionals are not fully aware of these risks." Further, by requiring the addition of the Black Box warning, the FDA "aims to make sure patients and medical providers have the information available to make informed treatment decisions."

PARTIES

7. Plaintiff is a competent individual over the age of 18. Plaintiff is a citizen and resident of Merced County, California. At all times relevant herein, Plaintiff was a citizen and resident of California. At all relevant times herein, Plaintiff was prescribed Singulair® in California. Plaintiff ingested Singulair® in California and sustained injuries therefrom in California.

8. Plaintiff was prescribed Singulair from 2010 to 2021. Many or all of Plaintiff's prescriptions were filled with branded Singulair. Some may have also been filled with generic Singulair. Plaintiff used Singulair as prescribed. As a direct and proximate result of ingesting

[1] Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., "Full Prescribing Information: Singulair® (montelukast sodium) Tablets, Chewable Tablets, and Oral Granules [US Patent No. 5,565,473]," Reference ID: 3106826 (Whitehouse Station, NJ: Merck & Co., Inc., 1998, revised Mar. 2012): 3-4, § 5.4: Neuropsychiatric Events; 6-7, § 6.2: Post-Marketing Experience. Accessed at https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/021409s036lbl.pdf.

Singulair®, Plaintiff suffered neuropsychiatric injury including major depressive disorder, suicidality, generalized anxiety disorder.

9. Plaintiff became symptomatic while using Singulair®.

10. Had Plaintiff or the prescriber known that Singulair® could cause Plaintiff to suffer neuropsychiatric events, theprescriber would not have prescribed Singulair®, Plaintiff would not have ingested Singulair®. Plaintiff has incurred medical expenses and will continue to incur expenses in connection with medical treatment as a result of these injuries, which were caused by Merck Defendants' conduct with respect to Singulair®'s design, labeling, manufacture, marketing, and sale. Plaintiff has endured and will continue to endure pain, suffering, mental anguish, trauma, and loss of enjoyment of life as a result of these injuries, have suffered lost earnings and/or a loss of earning capacity, and other injuries and damages to be proven at trial.

11. On information and belief, Merck Defendants are, and at all relevant times herein were, multi-national pharmaceutical corporations organized under the laws of New Jersey, with their principal place of business at 2000 Galloping Hill Road, Kenilworth, New Jersey 07033, and doing business in California. On information and belief, Merck Sharp & Dohme Corp. is, and at all relevant times was, registered with the California Secretary of State to do business in California.

12. Merck Defendants had exclusivity with respect to Singulair® and were the exclusive manufacturers, distributors, and sellers of Singulair® from 1998 to mid-2012. Merck Defendants have maintained control of brand name Singulair® at least into 2020 and possibly still maintain control.

13. On information and belief, the Merck Defendants "spun off" Singulair to their subsidiary, Organon & Co., sometime after the FDA ordered Merck to add the Black Box warning to Singulair's label. On information and belief, Organon & Co. is, and at all relevant times herein was, a corporation organized under the laws of Delaware, with a principal place of business at 30 Hudson Street, Floor 33, Jersey City, New Jersey 07302, and doing business in California. On information and belief, Organon LLC is a subsidiary of Organon & Co. that distributed Singulair to Californians, including Plaintiff. On information and belief, Organon LLC is, and at all relevant times herein was, a Delaware limited liability company with a principal place of business at 30

Hudson Street, Floor 33, Jersey City, New Jersey 07302. On information and belief, Organon & Co. and Organon LLC ("Organon") are, and at all relevant times were, registered with the California Secretary of State to do business in California.

14. On information and belief, subject to discovery regarding the relationship of the Merck Defendants to Organon, either Merck Defendants or Organon may be liable for injuries caused by Singulair after FDA directed a black box warning to be added to Singulair before it was added and physicians, pharmacists and patients were appropriately notified.

15. Plaintiff is informed and believes, and thereon alleges that, at all relevant times, the Merck Defendants and after transfer of the Singulair NDAs to it, Organon, conducts and at all relevant times conducted substantial, continuous business in California.

16. The Merck defendants manufactured, marketed and sold millions of Singulair pills, including the actual Singulair pills that Plaintiff used in California during and prior to 2012.

17. Since 2012, the Merck defendants have continued to manufacture, market, and sell Singulair in California at least into 2020 and either the Merck Defendants or Organon did so after 2020.

18. On information and belief, Merck Defendants and/or Organon may have subsequently manufactured, marketed and sold the actual Singulair pills used by Plaintiff in California.

19. Merck defendants engaged in an extensive campaign to educate physicians in California about the alleged benefits of Singulair, and further misrepresented the safety of Singulair to physicians in California during this campaign.

20. Merck Defendants engaged in extensive Direct-to-Consumer advertising in California including print ads in magazines sold in California as well as television advertising on television channels airing in California.

21. Plaintiff is ignorant of the true names and capacities of defendants sued herein as Does 1 through 10 and therefore sue these defendants by such fictitious names pursuant to California Code of Civil Procedure section 474. Plaintiff is informed and believes, and upon such information and belief, alleges, that each of the defendants designated as a Doe are legally responsible in some

manner for the events and happenings and caused damages, as alleged herein. Plaintiff will seek leave of the Court to amend this Complaint to show the true names and capacities of the defendants, designated as Does, when the same has been ascertained.

22. Plaintiff is informed and believes, and on that basis alleges, that at all times mentioned herein, there existed a unity of interest and ownership among Defendants and each of them, such that any individuality and separateness between Defendants, and each of them, ceased to exist. Defendants and each of them, were the successors-in-interest and/or alter egos of the other Defendants, and each of them, in that they purchased, controlled, dominated and operated each other without any separate identity, observation of formalities, or other manner of division. To continue maintaining the façade of a separate and individual existence between and among Defendants, and each of them, would allow Defendants to perpetrate a fraud and an injustice.

23. Plaintiff is informed and believes, and on that basis alleges, that at all times mentioned herein, Defendants and each of them were the agents, representatives and/or employees of each and every other Defendant. In doing the things hereinafter alleged, Defendants and each of them, were acting within the course and scope of said alternative personality, capacity, identity, agency, representation and/or employment and were within the scope of their authority, whether actual or apparent. Plaintiff is informed and believes, and on that basis alleges, that at all times mentioned herein, Defendants and each of them were the trustees, partners, servants, joint venturers, shareholders, contractors, and/or employees of each and every other Defendant, and the acts and omissions herein alleged were done by them, acting individually, through such capacity and within the scope of their authority, and with the permission and consent of each and every other Defendant and that said conduct was thereafter ratified by each and every other Defendant, and that each of them is jointly and severally liable to Plaintiff.

JURISDICTION AND VENUE

24. Venue is proper in this Court because Plaintiff is a citizen and resident of Merced County, California. During and prior to 2012, Plaintiff purchased and used Merck Defendants' Singulair in Merced County, and thereafter may have used generic and/or branded Singulair in Merced County. All of the Singulair ingested in California caused Plaintiff's injuries in that county.

Further on information and belief, Defendants made misrepresentations regarding the safety of Singulair to physicians in Merced County, California.

25. The California Superior Court has jurisdiction over all Defendants because, based on information and belief, each is a corporation and/or entity and/or person organized under the laws of having its principal place of business in the State of California, a foreign corporation or association authorized to do business in California and registered with the California Secretary of State, or that has sufficient minimum contacts in California, is a citizen of California, or otherwise intentionally avails itself of the California market so as to render the exercise of jurisdiction over it by the California courts consistent with traditional notions of fair play and substantial justice.

26. Further, Defendants have each purposefully availed themselves of the benefits and protections of the laws within the State of California. Collectively, Defendants conduct substantial, continuous, and systemic business in California and have had sufficient contact with California such that the exercise of jurisdiction would be consistent with the traditional notions of fair play and substantial justice.

FACTUAL ALLEGATIONS

A. Merck's Discovery of Montelukast

27. Merck Defendants discovered the anti-asthmatic properties of montelukast, the active ingredient in Singulair® and were granted U.S. Patent No. 5,565,473 on October 15, 1996, which expired on August 3, 2012. FDA first approved Singulair® for clinical use in 1998.

28. Singulair® has become a ubiquitous monotherapy treatment as an alternative to, and as an add-on therapy to inhaled corticosteroids (ICS) such as fluticasone. Approximately 9.3 million patients received a dispensed montelukast prescription from U.S. outpatient pharmacies in 2018, with 2.3 million of these being children younger than 17 years.[2]

29. Singulair® (montelukast) is a leukotriene receptor antagonist that binds with high

[2] U.S. Food and Drug Administration, Drug Safety Communications, *FDA requires Boxed Warning about serious mental health side effects for asthma and allergy drug montelukast (Singulair®); advises restricting use for allergic rhinitis: Risks may include suicidal thoughts or actions*," 3-4-2020 FDA Drug Safety Communication (Mar. 4, 2020) (citing IQVIA Total Patient Tracker™. Year 2018. Data extracted June 2019). Accessed at https://www.fda.gov/media/135840/download.

affinity and selectivity to the cysteinyl leukotriene receptor-1 (CysLTR1) in order to prevent this receptor from interacting with leukotrienes, which are inflammatory mediators. Such binding consequently assists in inhibiting many of the physiological actions elicited by CysLTs at the receptor which could have facilitated asthma or allergic rhinitis. As an example, montelukast modulates expression of CysLTR1 and CysLTR2 in airway eosinophilic (i.e., high count of white blood cells) inflammation of OVA-induced asthmatic mice because the drug functions in bodies as a CysLT1 receptor antagonist.[3]

30. Cysteinyl leukotrienes (CysLT) are eicosanoids (i.e., signaling molecules) that are released by various types of cells, including mast cells and eosinophils, both of which are implicated in allergy and anaphylaxis as well as the immune system. When these CysLT bind to their corresponding CysLT receptors (e.g., CysLT binding to CysLT1R), they may act to up- or down-regulate the receptor and its coordinating effect. For example, CysLT1 binding to CysLT1 receptors found on smooth muscle cells in respiratory airways simulates specific cell activities that then facilitate the underlying pathophysiology of asthma and allergic rhinitis.

31. Facilitating conditions for asthma include CysLT-mediated airway bronchoconstriction, vascular permeability, occluding mucous secretion, and eosinophil recruitment. In allergic rhinitis, nasal mucosa release CysLTs when exposed to allergens like pollen during both early- and late-phase reactions and then participate in eliciting the prototypical symptoms of allergic rhinitis like a congested nose and congested airway. Simply put, if allergens (e.g., dust and pollen) are the gasoline and CysLTs are the gas pedal that drive the asthma and allergies engine, Singulair® hits the brakes.

B. Singulair Crosses the Blood-Brain-Barrier and Causes Neuropsychiatric Events.

a. Introduction to the Blood-Brain-Barrier

32. Montelukast crosses the blood-brain barrier (BBB), which is a semi-permeable

[3] Zhang YJ, Zhang L, Wang SB, Shen HH, Wei EQ. Montelukast modulates lung CysLT(1) receptor expression and eosinophilic inflammation in asthmatic mice. *Acta Pharmacol Sin.* 2004;25(10):1341-1346 (Finding that montelukast inhibited the up-regulation of the CysLT1 receptor in airway eosinophilic inflammation of ovalbumin- induced (i.e., egg whites) asthmatic mice.

(i.e., partial porous) membrane of endothelial cells (blood and lymphatic vessel lining) that is highly selective in preventing solutes in circulating blood from non-selectively entering the extracellular fluid (e.g., cerebrospinal fluid) and thereby interacting with neurons in the central nervous system (CNS). The CNS influences activity within all of the parts of the body and is constituted primarily by the brain and spinal cord. Neurons function to communicate with other cells via connections called synapses. Neurons are like telephones in that they receive signals and synapses are similar to telephone lines that carry signals.

33. The function of the BBB is to protect the brain from circulating pathogens and thereby render bloodborne brain infections rare. No antibodies, only certain antibiotics, and exceedingly few drugs in general may pass the BBB and thereby have an impact on the CNS.

34. The clinical significance of the BBB is due to its difficulty as a drug target to overcome. Difficulty may be attributed to its 100% exclusion of large-molecule neurotherapeutics and 98% exclusion of all small-molecule drugs (e.g., anti-depressants like Prozac, anxiolytics like Xanax).[4] In terms of size and rough complexity, if a small-molecule druglike aspirin (21 Daltons) were a bicycle (~ 20 lbs), a large-molecule drug or small biologic like human growth hormone (~3,000 Daltons) would be a Toyota Prius (~ 3,000 lbs), and a large biologic like immunoglobulin G antibody (~ 25,000 Daltons) would be an F-16 fighter jet (~ 25,000 lbs without fuel).[5]

35. Small molecules are considered anything less than 900 Daltons. A molecular weight of 400 Daltons or less increases a drug's chances of penetrating the CNS.[9] Montelukast weighs 608.18 Daltons.

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[4] See, e.g., Pardridge, William M. "The Blood-Brain Barrier and Neurotherapeutics." *NeuroRx*. 2005 Jan; 2(1): 1—Doi: 10.1602/neurorx.2.1.1; Pardridge. "The Blood-Brain Barrier: Bottleneck in Brain Drug Development." *NeuroRx*. 2005 Jan; 2(1): 3—14. Doi: 10.1602/neurorx.2..3

[5] Deepak Gupta et al. "A CMO Perspective on Quality Challenges for Biopharmaceuticals," *BioProcess Int'l* (Oct. 1, 2013, 9:00 AM), accessed at http://www.bioprocessintl.com/manufacturing/ antibody-non- antibody/a-cmo-perspective-on-quality-challenges-for-biopharmaceuticals-347335; *See also*, McNally, Eugene J., and Jayne E. Hastedt. "Development of Drug Products: Similarities and Differences Between Protein Biologics and Small Synthetic Molecules." In *Protein Formulation and Delivery*, 2nd ed. Edited by Eugene J. McNally and Jayne E. Hastedt. Drugs and the Pharmaceutical Sciences, Vol. 175 (Boca Raton, FL: CRC PressTaylor & Francis Group, 2008): 327—333, 328—329.

36. Additionally, molecules with less than 8 hydrogen bonds have an increased likelihood of penetrating the BBB. These are weak intermolecular (i.e., between molecules) bonds between a lone pair electron "donor" and an electron "acceptor." If the "acceptor" is the team, the lone pair "donor" is the person who is getting picked last. Montelukast has 4 hydrogen bond acceptors and 2 hydrogen bond donors. Rendering the drug capable of having only 6 hydrogen bonds. Because of this, montelukast has an inherent increased likelihood of penetrating the BBB.

37. In order to deliver neurotherapeutic drugs to the brain to treat illnesses such as depression, schizophrenia, and obsessive-compulsive disorder, they must be able to cross the BBB. More lipid soluble or lipophilicity molecules are better able to penetrate the CNS.[6] Montelukast has been proven more lipid soluble than its sister class drug, Zafirlukast. In other words, because montelukast "likes" dissolving in fats or oils more than zafirlukast, montelukast is better able to cross the BBB.[7]

38. Because montelukast crosses the BBB, it exerts a systemic effect upon the CNS that results in, among other things, adverse neuropsychiatric events.

b. Singulair Crosses the Blood-Brain-Barrier

39. Montelukast crosses the BBB and thereby accumulates in the central nervous system (CNS), which is constituted by the brain and spinal cord. This drug accumulation occurs with both oral and intravenous doses, and in both humans and animals:

> Most importantly, **in a human subject taking 10 mg per day montelukast, that is, the approved dose to treat asthma, we detected [oral] montelukast in the serum and in the CSF** in a similar concentration as in the rats (Supplementary Fig. 1a), suggesting that the standard 10 mg per day dose in humans is sufficient to reach a therapeutic dose in the CSF. In addition, a re-analysis of the original CNS pharmacology data of montelukast27indicates a significant BBB penetrance of the drug (Supplementary Fig. 1b). **These data clearly demonstrate that orally administered montelukast does cross the BBB in a therapeutic dose**, and that age-dependent differential BBB integrity does not affect the capacity of montelukast to enter the brain…

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[6] E.g., Pardridge, William M., "Drug transport across the blood-brain barrier," J Cereb Blood Flow Metab. 2012 Nov; 32(11): 1959–1972. Published online 2012 Aug 29. doi: 10.1038/jcbfm.2012.126

[7] See Mougey, Edward B.; Hua Feng; Mario Castro, Charles G. Irvin, and John J. Lima, "Absorption of Montelukastis Transporter Mediated: a Common Varient of OATP2B1 is Associated with Reduced Plasma concentrations and Poor Response," [Author manuscript; available in *PMC* 2010 Feb 1] *Pharmacogenet Genomics*, 2009 Feb; 19(2): 129–138. doi: 10.1097/FPC.0b013e32831bd98c.

> Remarkably, montelukast serum levels [following intravenous drug administrations in rats] were almost identical to the maximum plasma concentrations in humans after oral administration of the clinical dose of 10 mg montelukast daily... illustrating that the animals were treated with montelukast in adose that pharmacologically resembles the one that is approved forits use in humans.[8]

40. Studies show that expression of the CysLTR1 (including that bound with montelukast) is not limited to the lungs. Instead, it occurs in different cells in the brain, including microvascular endothelial cells—components of the blood brain barrier. Pre- clinical studies of human and animal model tissue implicate CysLTR1 antagonists (e.g., Singulair®/montelukast, Onon/pranlukast, and Accolate/zafirlukast) as exerting effects upon traumatic brain injuries (TBI), ischemic brain injuries (e.g., stroke, TIA), cold-induced brain injuries, multiple sclerosis, auto-immune encephalomyelitis, Alzheimer's disease, and Parkinson's disease.[9] Activation of CysLTR1 is associated in animals with facilitating pathogen entry into the brain by disrupting the Blood Brain Barrier (BBB).[10] Among these pathogens are HIV-1 and *Escherichia coli*-mediated meningitis.[11] Furthermore, "[i]t has been demonstrated that [Singulair®] could increase the proliferation of neuronal precursor cells in vitro through the receptors CysLT1R and GPR17 [(G protein-coupled receptor 17)]."[12] Accordingly, although "expression of the CysLT1R in the normal human brain is very low/non-existent," montelukast blockades GPR17 and thereby "strongly elevate[s] neural stem and progenitor proliferation."[13] In other words, montelukast affects nerve cell

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[8] Marschallinger, J., Schäffner, I., Klein, B. *et al.* Structural and functional rejuvenation of the aged brain by an approved anti-asthmatic drug. *Nat Commun* 6, 8466 (2015), 4, 10. https://doi.org/10.1038/ncomms9466. (Emphasesadded).

[9] Ghosh A, Chen F, Thakur A, Hong H (2016). "Cysteinyl Leukotrienes and Their Receptors: Emerging Therapeutic Targets in Central Nervous System Disorders". CNS Neuroscience & Therapeutics. 22 (12): 943-951. doi: 10.1111/cns.12596. PMC 6492851. PMID 27542570.

[10] Bertin J, Jalaguier P, Barat C, et al. Exposure of human astrocytes to leukotriene C4 promotes a CX3CL1/fractalkine-mediated transmigration of HIV-1-infected CD4 + T cells across an in vitro blood–brain barriermodel. Virology 2014;454–455:128–138.

[11] Zhu L, Maruvada R, Sapirstein A, et al. Arachidonic acid metabolism regulates Escherichia coli penetration of the blood-brain barrier. Infect Immun 2010;78:4302–4310.

[12] Yohanna Eriksson, Martina Boström, Asa Sandelius Kaj Blennow, Henrik Zetterberg, Georg Kuhn, and Marie Kalm, The anti-asthmatic drug, montelukast, modifies the neurogenic potential in the young healthy and irradiated brain, *Cell Death and Disease* 9:775 (2018), 5. Doi 10.1038/s41419-018-0783-7. (citing Huber, C. et al. Inhibition ofleukotriene receptors boosts neural progenitor proliferation. *Cell. Physiol. Biochem.* 28, 793-804 (2011). doi: 10.1159/000335793.).

[13] Sansing-Foster, Veronica V., Ivone E. Kim, Dipti Kalra, Efe Eworuke, Lockwood G. Taylor, Lisa M. Harinstein,and

growth by expressing the activity of receptors.

41. Singulair® accumulates in the brain at a rate that is higher than its accumulation in the lungs:

> Although montelukast was so far always considered as a drug with only limited CNS penetration, careful re-analysis of the original pharmacokinetic report on montelukast reveals that one hour after i.v. drug administration, a substantial amount of radioactive equivalents of [C14] montelukast (~1/10 of the plasma levels) had reached the brain (Supplementary Fig. 1b). Most remarkably, while in plasma (and most other organs, for example, lung and muscle) montelukast levels strongly decreased within 24 h, the amount of montelukast in the brain increased. As a consequence, **24 h after drug injection, montelukast levels in the brain were even higher than in plasma** (Supplementary Fig. 1b), suggesting the existence of an active transport mechanism for montelukast through the BBB.

42. Singulair® accumulates in the brain because of its binding affinity to a BBB transporter:

> Indeed, montelukast is taken up from the intestine into the blood stream by the organic anion-transporting polypeptide (OATP)2B1, a transporter that is expressed also by endothelial cells of brain capillaries. Also, **the majority (99%) of montelukast in plasma is bound to proteins, mainly albumin, providing a BBB transport mechanism as albumin has been shown to act as a carrier through the BBB. The potential of montelukast to enter the CNS is further strongly supported byour present pharmacokinetic results obtained from rats** (Supplementary Fig. 1a).

43. Pre-clinical data also provide ample evidence of how montelukast enters into the brain:

> Strikingly, montelukast was also detected in the CSF in a human asthma patient, who was on the approved 10 mg per day dose of montelukast, and levels in serum and CSF were almost identical to the concentrations found in rats treated with 10 mg kg^{-1} montelukast (Supplementary Fig. 1a). **Entry of montelukast intothe CNS is further supported by the plethora of preclinical data on the effects of systemic montelukast treatment on brain structure and function.** In various animal models of neurodegenerative diseases, including a model of kainic acid-induced loss of memory function, an acute Huntington's disease model of quinolinic acid and malonic acid injection-induced degeneration of striatal neurons, and a β-amyloid injection model of Alzheimer's disease, treatment with montelukast attenuated behavioural deficits, which was accompanied by structural

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Monica Munoz, "Neuropsychiatric Events with Use of Montelukast in Pediatric Patients," *FDA Briefing Document: Pediatric Advisory Committee Meeting*, (Sept. 27, 2019), p. 14, § 1.4.4. Accessed at https://www.fda.gov/media/131035/download.

brain changes such as inhibition of neuroinflammation and reducedneuronal cell death.[14]

44. Animal studies demonstrate that Singulair® administered orally can be found in the brain and cerebrospinal fluid (CSF) found in the subarachnoid space between the two innermost (arachnoid mater and pia mater) of three protective membranes covering the brainand spinal cord:

> The biologic mechanisms underlying the neuropsychiatric events associated with montelukast treatment are currently not well understood. However, evidence from animal studies suggests that montelukast could act directly on cells in the brain. Orally administered montelukast (10 mg/kg/day, 7 days) was **detectable in brain tissue and cerebrospinal fluid (CSF)** in rats, providing evidence for its **ability to cross the blood-brain barrier.**[15]

These studies' findings were cited within the FDA's Briefing Document re: Singulair®.[16] Thus, taking Singulair® results in the accumulation of its active ingredient, montelukast, in brain tissue and cerebrospinal fluid.

c. Because Singulair® (Montelukast) Crosses the Blood-Brain-Barrier, It Can and Does Cause Neuropsychiatric Events.

45. The risk of new neuropsychiatric events is greater in pediatric patients who take Singulair®. "Children with asthma who experienced suicidality (i.e., suicidal thoughts), depression, tics, tremors, stuttering, agitation, and night terrors. A new-onset neuropsychiatric event [have]

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[14] Marschallinger (2015), 10 (Emphases added); see also, Zhang WP, Hu H, Zhang L, et al. Expression of cysteinyl leukotriene receptor 1 in human traumatic brain injury and brain tumors. *Neurosci Lett.* 2004;363(3):247-251; LenzQF, et al., *Neuroscience*, 2014). Doi: 10.1016/j.neulet.2004.03.088.

[15] Zhao R, Shi WZ, Zhang YM, et al. Montelukast, a cysteinyl leukotriene receptor-1 antagonist, attenuates chronic brain injury after focal cerebral ischaemia in mice and rats. *J Pharm Pharmacol.* 2011;63(4):550-557; Zhang CT, Lin JR, Wu F, et al. Montelukast ameliorates streptozotocin-induced cognitive impairment and neurotoxicity in mice. *Neurotoxicology.* 2016;57:214-222 (Emphasis added). This study was also cited during the FDA hearings regarding Singulair®. Aladdin, Meena M., Ph.D., Health Researcher, Public Citizen's Health Research Group, "Testimony Before the FDA's Pediatric Advisory Committee and Drug Safety and Risk Management Advisory Committee – Neuropsychiatric Events with Use of Montelukast in Pediatric Patients," FDA.gov (Sept. 27, 2019). Accessed at https://www.fda.gov/media/131487/download. (quoting Food and Drug Administration. Guidance for industry: Warnings and precautions, contraindications, and boxed warning sections of labeling for human prescription drug and biological products — content and format. October 2011. https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM075096.pdf. Accessed September 26, 2019).

[16] FDA Briefing Document, p. 14, § 1.4.4 (citing Volpe C, Kalra D, A. N. *Pharmacovigilance Review of Neuropsychiatric and Churg-Strauss Syndrome* (Feb. 21, 2014); Kalra D, Gatti J, T P. *Pediatric Postmarketing Pharmacovigilance and Drug Utilization Review of Montelukast* (September 2, 2014)).

nearly twice the odds of having been prescribed montelukast in the year before their event."[20] Furthermore, "children prescribed montelukast for asthma management hadnearly twice the odds of neuropsychiatric events, compared with those on other asthma maintenance medications.[21]

46. Additionally, a 2016 retrospective analysis of Individual Case Safety Reports (ICSRs) recorded up to January 1, 2015, in the World Health Organization's (WHO) database (VigiBase®), pulling from over 20 million reports of global suspected adverse effects ofmedicines. Their findings were as follows:

> Neuropsychiatric disorders as side effects of montelukast were more frequently reported for children than for adults. Infants andchildren seem to be more prone to sleep disturbances, whereas adolescents present symptoms of depression/anxiety and psychotic reactions more often. Suicidal behavior and completedsuicide appear to be more frequently reported than previously thought in practice...Practitioners should be aware of the risk of neuropsychiatric events associated with montelukast use, andshould advise the patient and report new cases.[17]

Thus, the neuropsychiatric dangers posed by Singulair® are much greater for children than for adults. Children with new onset neuropsychiatric events are twice as likely to have taken Singulair®, and children who are taking Singulair® are twice as likely to have neuropsychiatric events when compared with those taking other drugs (e.g., inhaled corticosteroids). This is significant because inhaled corticosteroids are known to have "**severe adverse psychological effects including psychosis**"[18] which can also "manifest in cognitive disorders, behavioral changes, and frank psychiatric disease."[19]

47. The risk of neuropsychiatric events associated with taking Singulair® are greaterthan those associated with taking ICS (e.g., albuterol). "In the real-life setting, children initiatedon montelukast experience **a notable risk of neuropsychiatric ADRs leading to drug cessation**, that

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[17] Ana Aldea Perona, Mar García-Sâiz, Emilio Sanz-Álvarez. Psychiatric Disorders and Montelukast in Children: A Disproportionality Analysis of the VigiBase®. *Drug Safe.* (Springer, 2016: New York, NY) 39:69-78, 69; see 76. Doi: 10.1007/s40264-015-0360-2. (n = 14,670 ICSRs, 2,630 neuropsychiatric events in people aged <18 years).

[18] Glockler-Lauf SD, Finkelstein Y, Zhu JQ, Feldman LY, To T. "Montelukast and Neuropsychiatric Events inChildren with Asthma: A Nested Case-Control Study. *Journal of Pediatrics.* 2019;209:176-182.e4. doi: 10.1016/j.jpeds.2019.02.009. (n = 898 NAE, 3,497 matched controls, p = 0.01).

[19] Linda B. Drozdowicz and J. Michael Bostwick, "[Review:] Psychiatric Adverse Effects of Pediatric Corticosteroid Use," *Mayo Clin Proc.* June 2014: 817—834. Doi: http://dx.doi.org/10.1016/j.mayocp.2014.01.010.

is significantly higher than that associated with [inhaled corticosteroids] ICS."[20]

48. Suicidality (i.e., suicidal thoughts) and suicide are a very real risk of taking Singulair®. "Suicidal behavior and completed suicide appear to be more frequently reported than previously thought in practice...Practitioners should be aware of the risk of neuropsychiatric events associate with montelukast use and should advise the patient and report new cases." (n = 14,670 Individual Case Safety Reports for montelukast).[21] Additional studies have found,

> "[M]ontelukast is associated with neuropsychiatric adverse drug reactionssuch as depression and aggression [and nightmares in children]."[27] Additionally, "[adverse drug reactions in published case reports] includedagitation, anxiety, depression, sleep disturbance, hallucinations, **suicidal thinking and suicidality, tremor**, drowsiness, neuropathies, and seizures." Further, immune system, induction of hypersensitivity reactions, and hepatobiliary/pancreatic/uropoietic disorders "**are characterized by severe prognosis (i.e., neurological deficit and fatal hepatotoxicity.**[22]

49. Singulair® causes a decrease in neuronal proliferation (nerve growth) in the hippocampal neurogenic zone (part of the brain largely involved in things from short-term memory to long-term memory, and spatial memory). Montelukast can cause "**negative effects both acutely and after 2 weeks of daily administration of montelukast.**"[23] In short, giving Singulair® to healthy children can delay their nerve growth in the part of the brain that is most important to short-term memory, long-term memory, and spatial memory. Furthermore, alterations in the hippocampus have been linked to a variety of cognitive pathologies such as anxiety, depression, addiction and neurodegenerative diseases such as Parkinson's.[24]

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[20] Benard B, Bastien V, Vinet B, Yang R, Krajinovic M, Ducharma FM. "Neuropsychiatric adverse drug reactions in children initiated on montelukast in real-life practice." *Eur Respir J.* 2017 Aug 17;50(2). Doi: 10.1183/13993003.00148-2017. Print 2017 Aug. (n = 12; ci = 95%) (Cited by 5 other articles) (Emphasis added).

[21] Aldea Perona A, García-Sáiz M, Sanz Álvarez E. "Psychiatric Disorders and Montelukast in Children: A Disproportionality Analysis of the VigiBase (®)." *Drug Saf.* 2016 Jan;39(1):69-78. Doi: 10.1007/s40264-015- 0360-2. (Cited by 8 other articles) (Emphasis added); *See* Aladdin, Menna M. "Testimony Before the FDA's Pediatric Advisory Committee and Drug Safety and Risk Management Advisory Committee – Neuropsychiatric Events with Use of Montelukast in Pediatric Patients." Sept 27, 2019. Accessed at https://www.fda.gov/media/131487/download.

[22] Calapai G, Casciaro M, Miroddi M, Calapai F, Navarra M, Gangemi S. "Montelukast-induced adverse drug reactions: a review of case reports in the literature." *Pharmacology.* 2014;94(1-2):60-70. Doi: 10.1159/000366164.(Emphasis added).

[23] *Id* at 6.

[24] See 5. Sapolsky R. M., "Glucocorticoids and hippocampal atrophy in neuropsychiatric disorders," *Arch Gen Psychiatry.* 2000;57:925–935. Doi: 10.1001/archpsyc.57.10.925.

C. Defendants Knew the Risks of Neuropsychiatric Events but Failed to Warn Prescribers, Parents or Patients of the Risks, and Even Misrepresented the Safety of Singulair.

50. When Singulair was originally approved by the FDA, it had no warnings regarding neuropsychiatric events.

51. Merck knew that Singulair crosses the blood-brain-barrier from pre-clinical trials, conducted prior to original approval.

52. Specifically, Merck Defendants misled the FDA with purpose and intent in its original New Drug Application (NDA) 20.829 and 20.830 which were used to obtain FDA approval for Singulair®5mg intravenous dosing. The footnotes to Table 4 of said NDAs state "only trace amounts were detected in the brain" and "radioactivity in all tissues declined with time, and the remaining radioactive equivalents in tissues were very low at 24 hour post dose". However, Table 4 in factdemonstrates the amount of radiolabeled drug in the brain increased over time and when lookedat as a ratio of brain:plasma, 0.041:0.142, **the 24 hour interval the level in the brain is 3.46 times or 346% greater than in the plasma.** Furthermore, from 1 hour post administration to the 24 hour interval the radioactive level of drug in the **plasma decreased by 96.64%**, whereas the radioactive level of drug in the **brain increased by 21.36% if you are just looking at volume in each specific tissue and not a ratio of brain: plasma.** Despite this data being statistically significant, Merck Defendants neglected to study the effects on the brain in clinical trials and misled the FDA in the way they reported their data.[25]

53. Two years before it was permitted to sell Singulair® in the United States,Defendant Merck obtained a patent for montelukast. In the patent application, ***DefendantMerck claimed that montelukast is "useful in treating ...cerebral spasm,"***[26] admitting that at least by 1996, Merck Defendants knew montelukast could affect the brain. Nonetheless, the Singulair® label from the

[25] Merck, "Table 4: Radioactive Equivalents (ug/g or ug/ml) of 1[14]C|Montelukast in the Tissues of Rats Receiving 5 mg/kg i.v. (Mean ± SD; n=3) [Sponsors Table 17 Ref. G-1 Vol. 29 pp. G-65]" [brackets original], *NDA 20.829 and 20.830*, 13.

[26] U.S. Patent No. 5,565,473

day Merck Defendants began sales in 1998 contained no warning of Singulair®'s possible effect on the brain, let alone of neuropsychiatric events.

54. Two and a half years after approval, on August 2, 2001, the "Post-Marketing Experience" section of Singulair's label was changed to state that "dream abnormalities and hallucinations, drowsiness, irritability, agitation including aggressive behavior, restlessness [and] insomnia" have been observed.

55. This label change should have occurred earlier through the Changes Being Effected ("CBE") Process. Merck had Newly Acquired Information ("NAI"), which would have permitted Merck to make this label change under the CBE.

56. Specifically, Merck should have conducted new analysis of clinical and preclinical testing data. The NAI would have been derived from the new analysis.

57. On June 23, 2004, the term "insomnia" was changed to "trouble sleeping." Merck made this change using the "Changes Being Effected" process.

58. Just five days after Merck changed "insomnia" to "trouble sleeping," Merck overhauled Singulair's label using CBE.

59. "Psychomotor hyperactivity" was added to the overdose section of the label on June 27, 2005.

60. The 2005 revision should have been made earlier through the CBE process through reanalysis of existing preclinical and clinical data.

61. Through the CBE process, Merck added the term "suicide" and replaced "psychomotor hyperactivity" with the "anxiousness" in the "Post-Marketing Experience" subsection of the Package Insert and the "Less Common Side Effects" section of the patient package insert.

62. The NAI information that enabled Merck to add the term "suicide" on information and belief, would have also enabled Merck to add the term "suicidality," which should have been added and explained.

63. This should have triggered Merck to engage in reanalysis of the data already submitted to the FDA or conduct additional tests to determine the extent of the dangers of

neuropsychiatric injuries. Upon information and belief, Merck did not conduct a reanalysis or additional testing.

64. When Merck added the terms "suicide" and "anxiousness" through the CBE, Merck should have made the warnings regarding those injuries stronger.

65. On August 19, 2009, FDA approved revisions to the PRECAUTIONS and ADVERSE REACTIONS sections of the label.

66. These revisions should have been made earlier and when made should have been more pronounced based on information Merck knew or should have known from reanalysis of preclinical and clinical trials.

67. These revisions should have been more strongly worded based on the increasing body of publicly available scientific literature regarding montelukast.

68. These revisions should have been more strongly worded based on post-marketing surveillance information available to the Merck Defendants.

69. Merck used the CBE to add the term "disorientation" to the "Warnings, Precautions and Adverse Events" section of the label on April 14, 2010.

70. Again, using CBE Merck added the term "tic" to the "Post-Marketing Experience" and "Neuropsychiatric Events" sections of the Prescribing Information. On the same date, using the CBE, Merck added "uncontrolled muscle movements" to the Patient Information Leaflet.

71. These revisions should have been more strongly worded, more pronounced, and should have been made sooner based on all the "newly acquired information" available to Merck, including but not limited to reanalysis of clinical and preclinical studies, publicly available articles, and post-marketing information.

72. In June 2018, through CBE, Merck added the term "obsessive-compulsive symptoms" to several sections of the label.

73. On information and belief, using the CBE process, Merck should have strengthened all of the neuropsychiatric warnings, including those involving obsessive-compulsive symptoms prior to that time.

74. "Dysphemia (stutteting)" was added to the Singulair label on February 13, 2019,

through CBE.

75. In November 2017, several patient advisory groups petitioned the FDA to strengthen Singulair's warnings with regard to neuropsychiatric events.

76. On September 27, 2019, the Pediatric Advisory Committee and the Drug Safety and Risk Management Advisory Committee of the FDA held a hearing to discuss the patient advisory groups' requests.

77. Following that hearing, the FDA required the Merck defendants to add a black box warning to the Singulair label.

78. Merck Defendants and/or Organon revised the label to include the black box warning.

79. These revisions should have been made much sooner based on adverse event and other post-marketing information as well as reanalsysis of existing studies and scientific literature.

80. All of these revisions should have been made earlier and when made should have been more pronounced and should have included stronger language based on information Merck knew or should have known from reanalysis of preclinical and clinical trials.

81. All of these revisions should have been made earlier and when made should have been more pronounced and should have included stronger language based on information Merck knew or should have known from the increasing body of publicly available articles regarding montelukast.

82. All of these revisions should have been made earlier and when made should have been more pronounced and should have included stronger language based on information Merck knew or should have known from post-marketing surveillance information available to the Merck Defendants.

83. For example, by 2015, over a quarter of the adverse events reported to the FDA included neuropsychiatric adverse events, including serious adverse events, such as homicidal and suicidal ideation, psychosis, and hallucinations, totaling thousands of such reports and over 25% of the total adverse events reported. Furthermore, the United States General Accounting Office has testified before Congress that, "Experts believe that FDA's [Adverse Event Reporting System

(AERS) system [only] includes a n estimated 1 to 10 percent of adverse reactions."

84. Indeed, every year since Singulair®'s launch in 1998, neuropsychiatric adverse event reports involving children two months to 17 years of age have been filed with the FDA in connection with Singulair®. In 1998 alone, 10 neuropsychiatric adverse events involving children were reported. In 1999, an additional 83 adverse events were reported. Sixty-six more children using Singulair® suffered neuropsychiatric adverse events in 2000. By 2020, a total of 3,135 children suffered such events, as reported to the FDA, including242 children under 24 months of age. Furthermore, the United States General Accounting Office has testified before Congress that, "Experts believe that FDA's [Adverse Event Reporting System (AERS) system [only] includes a n estimated 1 to 10 percent of adverse reactions."[27]

85. Plaintiff would not have used Singulair if he knew the risks of neuropsychiatric events.

D. The NDA Holder (aka "Brand") is Responsible for Label Revisions. The ANDA Holders (aka "Generics") Must Make the Label on Generic Drugs Substantially the Same as the Brand.[28]

86. In August 2012, Merck's United States patent expired for Singulair. Immediately thereafter, the FDA approved a number of generic forms of Singulair for sale in the United States. Notwithstanding the availability of generic forms of Singulair Merck has continued to manufacture, distribute, and market Singulair in its brand-named form throughout the United States, including in California.

87. As the brand-name manufacturer of Singulair, Defendants had and have a duty to maintain the accuracy and adequacy of the label for Singulair for as long as the drug is on the market. As the brand-name manufacturer of Singulair, Defendants were not only in the best position to warn

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[27] Janet Heinrich (Assoc. Dir. Health Fin. And Pub. Health Issues, Health and Human Serv. Div.), "Adverse Drug Events: Substantial Problem but Magnitude Uncertain [GAO/T-HEHS-00-53]," *Testimony: Before the Committee on Health, Education, Labor, and Pensions, U.S. Senate* (United States General Accounting Office:Tues Feb. 1, 2000), 6. Accessed at https://www.gao.gov/new.items/he00053t.pdf.

[28] "Defendants" in this section refer to the Merck Defendants at least until 2020, and thereafter if the Merck Defendants continued to hold the NDA. If the NDA was transferred to Organon in 2020, these allegations apply to the Merck Defendants up to the time of transfer and to Organon thereafter.

of Singulair's harmful effects, but were also the only manufacturers with the unilateral authority under federal law to issue such a warning.

88. Generic manufacturers for the bioequivalent of Singulair have only the duty to ensure their labels for generic bioequivalent to Singulair are the same as the label used by the brand name manufacturer, here, Defendants. Indeed, such sameness is required. As such, Defendants exercised complete control over the contents of the generic drug label attached to any generic Singulair Plaintiff may have used.

89. As a result, Defendants knew that any deficiencies in the label for Singulair would be perpetuated in the label of its generic bioequivalent. Accordingly, it is foreseeable that the warnings included or omitted on the brand-name drug label would influence dispensing of the generic drug.

90. As the brand name manufacturer of Singulair, Defendants had and have a duty to update its warning label "as soon as there is a reasonable evidence of an association of a serious hazard with a drug; a causal relationship need not have been proved." 21 C.F.R. § 201.80(e).

91. As the brand name manufacturer of Singulair, Defendants could have, at any time, unilaterally updated the Singulair label without waiting for FDA preapproval in order to "add or strengthen a contraindication, warning, precaution, or adverse reaction" under the "changes being effected" regulation. 21 C.F.R. § 314.70(c)(6)(iii)(A). As the brand name manufacturer of Singulair, a part of Defendants' business was to give information about Singulair to the public and medical community upon which the safety of patients like Plaintiff, depend.

92. Insurance is available to a brand name manufacturer, like Defendants, to insure against liability arising from their failure to adequate warn of the risks associated with Singulair/Montelukast that Defendants knew or reasonably should have known.

TOLLING STATUTES OF LIMITATIONS

Discovery-Rule Tolling

93. Within the period of any applicable statute of limitations, Plaintiff could not have discovered through the exercise of reasonable diligence that Singulair® caused a significantly increased risk of adverse neuropsychiatric events.

94. Plaintiff did not discover, and did not know of, facts that would have caused a reasonable person to suspect that his injuries were caused by Defendants' concealment and suppression of the fact that individuals who ingested Singulair® were at significantly increased risk of developing neuropsychiatric events.

95. Plaintiff could not have reasonably discovered the true extent of Defendants' deception or suppression about Singulair®'s safety until the FDA required the Boxed Warning about the serious mental health side effects for Singulair® and the advisement on the restriction of use of Singulair®.

96. For these reasons, all applicable statutes of limitations have been tolled byoperation of the discovery rule.

A. Estoppel

97. Defendants were under a continuous duty to adequately disclose to and inform Plaintiff of the risk of developing neuropsychiatric events with Singulair®.

98. Defendants knowingly, affirmatively, and actively concealed, suppressed, ignored, or recklessly disregarded the true risks of developing neuropsychiatric events associated with Singulair® and never updated the drug's label to adequately disclose this risk.

99. Based on the foregoing, Defendants are estopped from relying on any statutes of limitations in defense of this action.

B. Continuing Tort

100. The continuing tort doctrine applies when there is a repeated or continuous injury and the tort is not completed until the last injury is inflicted or the wrongdoing ceases. In cases of continuing torts, the statutes of limitations do not begin to run until the date of the last tortious act.

101. Plaintiff used Singulair® over extended periods. Each time Plaintiff ingested Singulair®, it constituted a continuing tort.

102. The time period associated with Plaintiff's statute of limitations did not begin to run until, at the earliest, Plaintiff's last use of Singulair®.

CAUSES OF ACTION

FIRST CAUSE OF ACTION

STRICT LIABILITY - DESIGN DEFECT

(Against Merck Defendants and DOES 1-10, Inclusive)

103. Plaintiff incorporates by reference each preceding and succeeding paragraphs as though set forth fully at length herein.

104. At all times relevant, Defendants tested, developed, designed, labeled, manufactured, marketed, sold, distributed, advertised, and promoted Singulair®.

105. Singulair® is defective because it causes neuropsychiatric events. The risk of neuropsychiatric events from Singulair® ingestion, including but not limited to (a) agitation, aggressive behavior, or hostility; (b) attention problems; (c) bad or vividdreams; (d) depression; (e) disorientation or confusion; (f) feeling anxious; (g) hallucinations (seeing or hearing things that are not really there); (h) irritability; (i) memory problems; (j) obsessive-compulsive symptoms; (k) restlessness; (l) somnambulance (sleepwalking); (m) stuttering; (n) suicidal thoughts (suicidality) and actions; (o) tremor or shakiness; (p) trouble sleeping; and (q) uncontrolled muscle movements (tics) were actually known to and foreseeableto Merk Defendants at all times during the period which they manufactured and sold Singulair®.

106. The risks of neuropsychiatric injuries posed by Singulair® were reasonably foreseeable to Defendants.

107. The Singulair® used by Plaintiff was defectively designed in that (1) its risks outweighed its utility, and (2) safer, feasible alternative designs are and were at all times available. These safer alternative designs include (a) modifying montelukast itself to make it less likely to pass the BBB, (b) modifying Singulair® without modifying montelukast to make it less likely that montelukast would pass the BBB, (c) modifying Singulair®'s dosing regimen to enable prescribers to prescribe the lowest therapeutic dose, (d) modifying Singulair®'s instructions to enable prescribers to prescribe the lowest therapeutic dose, and instruct patients to take Singulair® when it is less likely to cross the BBB.

108. As further described above, the scientific community expressed concern about

the propensity of montelukast to cause an increased risk of neuropsychiatric events when ingested. From the time of Singulair®'s launch until the present day, various scientific literature, as further discussed above, has expressed concerns about an increased risk of adverseneuropsychiatric events in patients who ingest Singulair® (montelukast). Plaintiff was unaware of this scientific literature, but Defendants were aware of it.

109. The risk of Singulair® outweighs its benefits.

110. Specifically, the benefit of Singulair® is, at best, the treatment and/or prevention of asthma and hay fever symptoms. This benefit is significantly outweighed by the risks posed by Singulair®--the risk of permanent neuropsychiatric effects, and possibly even death.

111. Plaintiff and Plaintiff's prescriber had many alternatives, including other leukotriene receptor antagonists, inhaled corticosteroids, antihistamines, and a host of other pharmaceutical and non-pharmaceutical options to Singulair®. No reasonable consumer would select, from a slew of equally effective, or possibly more effective products, the one that causes neuropsychiatric effects.

112. Additionally or in the alternative, there are feasible alternative designs to Singulair®.

113. Singulair® is and at all times was defective, unreasonably dangerous, and unsafefor its intended purpose because, when ingested, it causes an increased risk of adverse neuropsychiatric events.

114. The risks of Singulair® causing neuropsychiatric injuries exist in part because montelukast crosses the blood-brain-barrier.

115. Defendants could have modified Singulair® in such a manner that it would not pass the blood-brain-barrier unabated.

116. They could have done this by changing the chemical montelukast itself.

117. Defendants had options, like modifying montelukast to be less lipid-soluble or modification of the hydrogen bonds to make passing the BBB more difficult.

118. This alternative design is feasible. Any of the three occasions when Merck Defendants requested approval of a new NDA, they could have presented this alternative to FDA.

119. Defendants also had options to modify Singulair® without modifying montelukast.

120. For example, Defendants could have added a faster acting anti-inflammatory to make

the BBB less permeable, or could have made an extended release tablet to decrease the amount of montelukast assaulting the BBB at any one time.

121. This alternative is feasible. Many drugs include two otherwise approved active ingredients, one of which is frequently anti-inflammatory. Further, the capsules of approved drugs are often designed for extended release.

122. Additionally, the dosing regimen of Singulair® was defectively designed.

123. Defendants could have created dosing options that would have allowed prescribers to prescribe the lowest therapeutic dose, but did not do so.

124. Singulair® is available in three "sizes": 4mg, 5mg, and 10mg. In other words, Merck's testing revealed that there is some significant difference in as small as one mg increments, yet it did not provide a one mg option. Even though Merck is aware of some significant difference in adding just one mg to a patient's dose (as in increasing from 4mg to 5mg), Merck made it impossible for a prescriber to increase a patient's dosage by just one mg in most circumstances. For example, if a prescriber wants to increase a dose from 5mg, the prescriber must double the dose to 10mg.

125. Simply creating additional dosing options is a feasible alternative design, as evidenced by the fact that Merck already created three doses. There is no reason to believe a fourth dosing option would be infeasible.

126. Furthermore, the instructions to prescribers were designed deficiently.

127. For example, Merck instructed prescribers to consider only a person's age when determining dosage, disregarding entirely weight, stage of development, severity of symptoms, and any other consideration.

128. Instructing prescribers to consider severity of symptoms and weight is the norm. It is feasible for Singulair®'s dosing regimen to fit the norm.

129. By way of another example, Merck also instructs prescribers to have patients ingest Singulair® before bed, even though the BBB is more susceptible when a person is sleeping.

130. Modifying instructions is feasible.

131. Thus, at the time Singulair® left Defendants' control, there were practical,

technically feasible, and safer alternative designs, that would have prevented the harm without substantially impairing the reasonably anticipated or intended function of Defendants' medications for asthma and allergic rhinitis.

132. Defendants' omission of any alternative designs renders Singulair® not reasonably safe.

133. Singulair®'s design defects existed at the time Singulair® left Defendants' possession and control.

134. Singulair® reached the intended consumers, handlers, and users throughout the United States, including Plaintiff, without substantial change in its condition as designed, manufactured, sold, distributed, labeled, and marketed by Defendants.

135. Plaintiff ingested Singulair® for an approved purpose and experienced neuropsychiatric injuries as a result.

136. Plaintiff ingested Singulair® without adequate knowledge of Singulair®'s dangerous characteristics.

137. At all times relevant, Plaintiff used Singulair® in an intended or reasonably foreseeable manner without knowledge of Singulair®'s dangerous characteristics.

138. Plaintiff could not have reasonably discovered the defects and risks associated with Singulair® or montelukast-containing products before or at the time of ingestion and useas a result of Defendants' suppression of, failure to obtain, or failure to provide scientific information linking montelukast to neuropsychiatric events.

139. The defects in Singulair® were substantial and contributing factors in causing Plaintiff's injuries, harms, losses, and damages and, but for Defendants' misconduct and omissions, Plaintiff would not have sustained injuries, harms, losses, and damages.

140. Had Plaintiff known of the defects in Singulair®, Plaintiff would not have taken Singulair®. Instead, Plaintiff would have taken a safer alternative to Singulair® that would not have exposed Plaintiff to neuropsychiatric events.

141. Plaintiff's injuries, harms, losses, and damages were directly and proximately caused by Singulair® and Singulair®'s defect while Plaintiff purchased and used Singulair® in a

reasonably foreseeable manner for which recovery is sought.

142. The benefits of Singulair®'s design are outweighed by the design's inherent riskof danger in causing neuropsychiatric events.

143. Defendants knowingly designed Singulair® with the design defect that causes Singulair® to cause an increased risk of neuropsychiatric events when ingested to maximize profits.

144. Defendants are therefore strictly liable for the damages caused to Plaintiff.

SECOND CAUSE OF ACTION

STRICT LIABILITY - FAILURE TO WARN

(Against Merck Defendants, Organon and DOES 1-10, Inclusive)

145. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein.

146. "Defendants" in this cause of action refers to Merck while it held the NDA and if it did so, to Organon during the period it held the NDA.

147. Defendants tested, developed, designed, labeled, manufactured, marketed, sold, distributed, advertised, and promoted Singulair® during the periods set forth above.

148. At all times relevant, Defendants had a duty to properly test, develop, design, manufacture, inspect, package, label, market, promote, sell, distribute, maintain, supply, provide proper warnings, and take such steps as necessary to ensure Singulair® did not cause users and consumers to suffer from unreasonable and dangerous risks.

149. At all times relevant, Defendants had a continuing duty to warn Plaintiff and Plaintiff's prescribers of the dangers associated with Singulair® use.

150. At all times relevant, Defendants could have provided adequate warnings or instructions regarding the full and complete risks of Singulair® and its active ingredient montelukast because Defendants knew or should have known of the unreasonable risks of harm associated with the use of Singulair® and montelukast. Such warnings could have been adequately disclosed in circumstances not limited to Singulair®'s labeling.

151. At all times relevant, Defendants failed to investigate, study, test, or promote the safety or to minimize the dangers to users and consumers of Singulair® and to those who would

foreseeably prescribe, use, or be harmed by Singulair®, including Plaintiff.

152. Despite the fact that Defendants knew or should have known that Singulair® posed a grave risk of harm, they failed to exercise reasonable care to warn of the dangerousrisks associated with its use. The dangerous propensities of Singulair® and its active ingredient, montelukast, as described above were either known to Defendants or scientifically knowable to Defendants through appropriate research and testing by known methods at the time Defendants distributed, supplied, or sold Singulair® and not adequately known to prescribing healthcare providers and end users and consumers, such as Plaintiff.

153. Defendants knew or should have known that Singulair® created significant risks of serious bodily harm to consumers, as alleged herein, and Defendants failed to adequately warn prescribing healthcare providers and consumers, i.e., the reasonably foreseeable users, of the risks of ingesting Singulair®. Upon information and belief, Defendants wrongfully concealed or suppressed information concerning the dangerous nature of Singulair® and its active ingredient, montelukast, and further made false and/or misleading statements concerning the safety of Singulair® and montelukast.

154. Singulair® is and at all times was defective and not reasonably fit, suitable, or safe for its intended purpose because Defendants designed Singulair® in a defective manner and failed to give adequate warnings or instructions at the time Singulair® left Defendants' control and after.

155. Defendants failed to provide adequate warnings of the dangers regarding the factthat Singulair® caused an increased risk of adverse neuropsychiatric events in individuals who ingested Singulair®.

156. Defendants failed to provide adequate warnings of the dangers regarding the factthat Singulair® ingestion increased the risk suffering from neuropsychiatric events, including but not limited to (a) agitation, aggressive behavior, or hostility; (b) attention problems; (c) bad or vivid dreams; (d) depression; (e) disorientation or confusion; (f) feeling anxious; (g) hallucinations (seeing or hearing things that are not really there); (h) irritability; (i) memory problems; (j) obsessive-compulsive symptoms; (k) restlessness; (l) somnambulance (sleepwalking); (m) stuttering; (n) suicidal thoughts (suicidality) and actions; (o) tremor or shakiness; (p) trouble

sleeping; and (q) uncontrolled muscle movements (tics).

157. Singulair®'s failure-to-warn defects existed at the time Singulair® left Defendants' control.

158. Defendants distributed Singulair® without sufficient warnings to notify Plaintiff's prescriber or Plaintiff of the dangers inherent in ingesting Singulair®.

159. Defendants knew or should have known that most physicians who prescribed Singulair® did not know or fully appreciate the seriousness of the risks associated with Singulair® or montelukast.

160. Plaintiff ingested Singulair® for an approved purpose and experienced neuropsychiatric events as a result of his Singulair® use.

161. Defendants knew or should have known that the minimal warnings disseminated with Singulair® were inadequate, failed to communicate adequate information on the dangers and safe use of Singulair®, and failed to communicate warnings and instructions that were appropriate and adequate to render the product safe for its ordinary, intended, and reasonably foreseeable uses.

162. Had Plaintiff or Plaintiff's physician known of the defects in Singulair®, Plaintiff would have been prescribed and would have ingested a safer alternative to Singulair® that would not have exposed him to increased risks of suffering neuropsychiatric events.

163. Plaintiff ingested Singulair® without knowledge of its dangerous characteristics.

164. Plaintiff's injuries, harms, losses, and damages were directly and proximately caused by Singulair®, including the lack, insufficiency, or adequacy of warning of Singulair®'s unreasonable dangers as set forth above while Plaintiff used Singulair® in a reasonably foreseeable manner for which recovery is sought.

165. Defendants had a duty to properly warn Plaintiff and Plaintiff's physician of the risks of Singulair® during the time when Plaintiff's prescriptions were being filled with Defendants' Singulair®. Defendants' breach of this duty proximately caused the injuries described herein.

166. Defendants' misrepresentations proximately caused Plaintiff's injuries.

167. Defendants are therefore strictly liable for the damages caused to Plaintiff.

168. Defendants' conduct, as described above, is also oppressive and malicious.

Defendants regularly risked the health and lives of consumers and users of Singulair®,including Plaintiff, with knowledge of Singulair®'s dangers. Defendants have made conscious decisions not to voluntarily sell Singulair without re-design, re-labeling, adequately warning, or adequately informing physicians and the public, including Plaintiff of the increased risk of developing neuropsychiatric events when ingesting Singulair®. Defendants are guilty of oppression, in that their conscious disregard for Plaintiff's rights subjected Plaintiff to cruel and unjust hardship of suffering neuropsychiatric injury, as described above. Further, Defendants are guilty of malice because their despicable conduct was willful or done with conscious disregard of the rights and safety of consumers, including Plaintiff. Defendants' misconduct therefore warrants an award of exemplary damages.

THIRD CAUSE OF ACTION

NEGLIGENCE

(Against Merck Defendants, Organon and DOES 1-10, Inclusive)

169. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein.

170. "Defendants" in this cause of action refers to Merck while it held the NDA and if it did so, to Organon during the period it held the NDA.

171. At all times relevant, Defendants had a duty to exercise reasonable care in the design, research, manufacture, marketing, advertisement, supply, promotion, packaging, sale, and distribution of Singulair®, including the duty to take all reasonable steps necessary to manufacture, promote, advertise, and/or sell a medication that was not unreasonably dangerous to consumers and users of the medication.

172. At all times relevant, Defendants had a duty to exercise reasonable care in the marketing, advertisement, and sale of Singulair®. Defendants' duty of care owed to consumers and the general public included providing accurate, true, and correct information concerning therisks of using Singulair® and appropriate, complete, adequate, and accurate warnings concerning the potential adverse effects of ingestion of Singulair® and its active ingredient, montelukast.

173. At all times relevant, Defendants knew or, in the exercise of reasonable care, should

have known of the hazards and dangers of Singulair® and specifically its increased risk of neuropsychiatric events when ingested.

174. Accordingly, at all times relevant, Defendants knew or, in the exercise of reasonable care, should have known that use of Singulair® could cause or be associated with Plaintiff's injuries, and thus, created a dangerous and unreasonable risk of injury to the users of Singulair®, including Plaintiff.

175. Defendants also knew or, in the exercise of reasonable care, should have known that users and consumers of Singulair® and their prescribing physicians and healthcare providers were unaware of or did not know or fully appreciate the seriousness and magnitude ofthe risks associated with use of Singulair® and montelukast.

176. Defendants breached their duty of reasonable care and failed to exercise ordinary care in the design, research, development, manufacture, testing, marketing, supply, promotion, advertisement, packaging, sale, and distribution of Singulair® in that Defendants manufactured but and produced a medication containing montelukast, knew or had reason to know of the defects inherent in Singulair® or had reason to know that a user's or consumer's ingestion of Singulair® created a significant risk of harm and unreasonably dangerous side effects, and failed to prevent or adequately warn of these risks and injuries.

177. Defendants were negligent in their promotion of Singulair® by failing to adequately disclose material risk information as part of their promotion and marketing of Singulair®, including the internet, television, and print advertisements. Nothing preventedDefendants from being honest in their promotional activities, and in fact, Defendants had a dutyto disclose the truth about the risks associated with Singulair® in their promotional efforts outside of the of the context of labeling.

178. Defendants had and have the ability and means to investigate, study, and test their products and to provide adequate warnings, and Defendants failed to do so. Upon information and belief, Defendants have wrongfully concealed information and have further made false and/or misleading statements concerning the safety of Singulair® and montelukast.

179. Defendants' negligence included:

a) Manufacturing, producing, promoting, formulating, creating, developing, designing, selling, advertising, and/or distributing Singulair® without thorough and adequate pre- and post-market testing;

b) Manufacturing, producing, promoting, formulating, creating, developing, designing, selling, advertising, and/or distributing Singulair® while negligently and/or intentionally concealing and failing to disclose the results of trials, tests, and studies of ingesting Singulair® and specifically its active ingredient, montelukast, and, consequently, the risk of serious harm associated with ingestion of Singulair®;

c) Failing to undertake sufficient studies and conduct necessary tests to determine whether Singulair® was safe for its intended use;

d) Failing to use reasonable and prudent care in the design, research, manufacture, and development of Singulair® so as to avoid the risk of serious harm associated with the ingestion of Singulair®;

e) Failing to design and manufacture Singulair® so as to ensure it was at least as safe and effective as other medications on the market treating the same and/or similar conditions;

f) Failing to provide adequate instructions, guidelines, and safety precautions to those persons Defendants could reasonably foresee would prescribe and use Singulair®;

g) Failing to adequately disclose to Plaintiff, Plainitff, physicians, users/consumers, and the general public that use and ingestion of Singulair® presented severe risks of developing neuropsychiatric events;

h) Failing to adequately warn Plaintiff, Plaintiff, physicians, users/consumers, and the general public that Singulair®'s risk of harm was unreasonable and that there were safer and effective alternative medications available to Plaintiff, prescribing physicians, and other consumers and Systematically suppressing or ignoring contrary evidence

about the risks,incidence, and prevalence of the side effects of Singulair® and montelukast- containing medications;

i) Representing that Singulair® was safe for its intended use when, in fact, Defendants knew or should have known that Singulair® was not safe or presented serious risks when used for its intended purpose;

j) Declining to make or propose any changes to Singulair®'s labeling or other promotional materials that would alert consumers, physicians, and the general public of the seriousness and magnitude of the risks of ingesting Singulair® and its active ingredient, montelukast;

k) Advertising, marketing, and recommending the use of Singulair® while concealing or failing to adequately disclose or warn of the dangers known by Defendants to be associated with or caused by the use of Singulair® and montelukast;

l) Continuing to disseminate information to consumers and physicians that indicates or implies that Singulair® is safe for use; and

m) Continuing the manufacture and sale of Singulair® with the knowledge that it was unreasonably unsafe and dangerous.

180. Defendants knew and/or should have known that it was foreseeable that individuals such as Plaintiff would suffer injuries as a result of Defendants' failure to exercise ordinary and reasonable care in the manufacturing, marketing, labeling, distribution, and sale of Singulair®.

181. Plaintiff and Plaintiff's prescriber did not know thenature and extent of the injuries that could result from the intended use of Singulair® or its active ingredient, montelukast. Absent Defendants' negligence, Plaintiff would not have developed neuropsychiatric events.

182. As a direct and proximate result of Defendants placing Singulair® into thestream of commerce, Plaintiff suffered injuries, harms, losses, and damages.

183. Defendants are therefore liable for Plaintiff's damages arising from Defendants' negligence.

184. Defendants' conduct, as described above, was not only negligent but it was also

oppressive and malicious. Defendants regularly risked the health and lives of consumers and users of Singulair®,including Plaintiff, with knowledge of Singulair®'s dangers. Defendants have made conscious decisions not to voluntarily re-design, re-label, adequately warn, or adequately inform physicians and the public, including Plaintiff of the increased risk of developing neuropsychiatric events when ingesting Singulair®. Defendants are guilty of oppression, in that their conscious disregard for Plaintiff's rights subjected Plaintiff to cruel and unjust hardship of suffering neuropsychiatric injury, as described above. Further, Defendants are guilty of malice because their despicable conduct was willful or done with conscious disregard of the rights and safety of consumers, including Plaintiff. Defendants' misconduct therefore warrants an award of exemplary damages.

FOURTH CAUSE OF ACTION

NEGLIGENCE MISREPRESENTATION

(Against Merck Defendants, Organon and DOES 1-10, Inclusive)

185. Plaintiff incorporates by reference each preceding and succeeding paragraphs as though set forth fully at length herein.

186. "Defendants" in this cause of action refers to Merck while it held the NDA and if it did so, to Organon during the period it held the NDA.

187. At all relevant times, Defendants designed, manufactured, tested (or not), packaged, labeled, marketed, advertised, promoted, supplied, distributed, sold, and/or otherwise placed Singulair/montelukast into the stream of commerce, and therefore owed a duty of reasonable care to avoid causing harm to those that consumed Singulair/montelukast, such as Plaintiff.

188. Defendants were negligent, reckless, and careless and owed a duty to Plaintiff to make accurate and truthful representations regarding Singulair/montelukast, Defendants breached their duty, thereby causing Plaintiff to suffer harm.

189. Defendants represented to Plaintiff, their physicians, and their prescriber via the media, advertising, website, social media, packaging, and promotions, among other misrepresentations described herein that Singular/montelukast was both safe and effective; consumption of Singulair/montelukast would not result in neuropsychiatric side effects; and

Singulair/montelukast was safe for their intended use when, in fact, Defendants knew or should have known the product was not safe for its intended purpose.

190. These representations were false. Because Singulair/montelukast crosses the blood-brain-barrier, it can and does cause negative neuropsychiatric events. The side effects were so significant that the FDA required a Black Box warning on Singulair.

191. Defendants knew or should have known these representations were false and negligently made them without regard for their truth. Defendants had a duty to accurately provide this information to Plaintiff. In concealing this information from Plaintiff, Defendants breached their duty. Defendants also gained financially from and as a result of their breach.

192. Defendants intended for Plaintiff, their physicians, and their prescriber to rely on these representations.

193. Each of these misrepresentations were material at the time they were made. In particular, each of the misrepresentations concerned material facts that were essential to the analysis undertaken by Plaintiff as to whether to purchase or consume Singulair/montelukast.

194. Plaintiff, their physicians, and their prescriber reasonably relied on these representations and were harmed as described herein. Plaintiff's reliance on Defendants' representation was a substantial factor in causing Plaintiff's harms. Had Defendants told Plaintiff the truth about the safety and composition of Singulair/montelukast, Plaintiff would not have consumed or purchased them.

195. Defendants' acts and omissions as described herein were committed in reckless disregard of Plaintiff's rights, interests, and well-being to enrich Defendants.

196. Plaintiff was injured as a direct and proximate result of Defendants' negligent misrepresentations regarding Singulair/montelukast as described herein. These injuries were, or should have been, reasonably foreseeable to Defendants.

197. Defendants are therefore liable for Plaintiff's damages arising from Defendants' misrepresentations.

FIFTH CAUSE OF ACTION

BREACH OF EXPRESS WARRANTY

(Against Merck Defendants, Organon and DOES 1-10, Inclusive)

198. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein.

199. "Defendants" in this cause of action refers to Merck while it held the NDA and if it did so, to Organon during the period it held the NDA.

200. At all relevant times, Defendants engaged in the business of testing, developing, designing, manufacturing, marketing, selling, distributing, and promoting Singulair®, which is defective and unreasonably dangerous to consumers, including Plaintiff, thereby placing Singulair® into the stream of commerce.

201. Defendants had a duty to exercise reasonable care in the research, development, design, testing, packaging, manufacture, inspection, labeling, distributing, marketing, promotion, sale, and release of Singulair®, including a duty to:

a. ensure that its products did not cause the user unreasonably dangerous side effects;

b. adequately warn of dangerous and potentially fatal side effects; and,

c. adequately disclose adverse material facts, such as the true risks associated with the use of Singulair®, when making representations to consumers and the general public, including Plaintiff.

202. The ability of Defendants to properly disclose those risks associated with Singulair® is not limited to representations made on the labeling.

203. At all relevant times, Defendants expressly represented and warranted to the purchasers of their products, by and through statements made by Defendants in labels, publications, package inserts, and other written materials intended for consumers and the general public, that Singulair® was safe to human health, effective, fit, and proper for its intended use. Defendants advertised, labeled, marketed, and promoted Singulair® representing the quality to consumers and the public in such a way as to induce their purchase or use, thereby making an express warranty that Singulair® would conform to the representations.

204. These express representations include incomplete or inadequate warnings and

instructions that purport, but fail, to adequately include the complete array of risks associated with use of Singulair®. Defendants knew and/or should have known that the risks expressly included in Singulair® warnings and labels did not accurately or adequately set forth the risks of developing the serious injuries complained of herein. Nevertheless, Defendants expressly represented that Singulair® products were safe and effective, that they were safe and effective for use by individuals such as Plaintiff, and/or that they were safe and effective as a medication.

205. The representations about Singulair®, as set forth herein, contained or constituted affirmations of fact or promises made by the seller to the buyer, which related to the goods and became part of the basis of the bargain, creating an express warranty that the goods would conform to the representations.

206. Defendants placed Singulair® into the stream of commerce for sale and recommended its use to consumers and the public without adequately warning of the true risks of developing the injuries associated with the use of Singulair®.

207. Defendants breached these warranties because, among other things, Singulair® was defective, dangerous, and unfit for use, did not contain labels representing the true and adequate nature of the risks associated with its use, and were not merchantable or safe for its intended, ordinary, and foreseeable use and purpose. Specifically, Defendants breached the warranties in the following ways:

i. Defendants represented through their labeling, advertising, and marketing materials that Singulair® was safe, and intentionally or negligently withheld and concealed information about the risks of serious injury associated with use of Singulair® and by expressly limiting or ignoring the risks associated with use within its warnings and labels; and

ii. Defendants represented that Singulair® was safe for use and intentionally or negligently concealed information that demonstrated that use of Singulair® created an increased risk of developing and causing NSEs, and that Singulair®, therefore, was not safer than alternatives available on the market.

208. Plaintiff detrimentally relied on the express warranties and representations of Defendants concerning the safety and/or risk profile of Singulair® in deciding to purchase and

obtain the product. Plaintiff reasonably relied upon Defendants to accurately and adequately disclose known defects, risks, dangers, and side effects of Singulair®. Plaintiff would not have purchased or used Singulair® had Defendants properly disclosed the risks associated with the product, either through advertising, labeling, or any other form of disclosure.

209. Defendants had sole access to material facts concerning the nature of the risks associated with Singulair®, as expressly stated within Singulair® warnings and labels, and knew that consumers and users such as Plaintiff could not have reasonably discovered that the risks expressly included in Singulair® warnings and labels were inadequate and inaccurate.

210. Plaintiff had no knowledge of the falsity, incompleteness, or inadequacy of Defendants' statements and representations concerning Singulair®.

211. Plaintiff used Singulair® as researched, developed, designed, tested, manufactured, inspected, labeled, distributed, packaged, marketed, promoted, sold, or otherwise released into the stream of commerce by Defendants.

212. Had the warnings, labels, advertisements, or promotional material for Singulair® accurately and adequately set forth the true risks associated with the use of Singulair®, Plaintiff's injuries, rather than expressly excluding such information and warranting that the product was safe for its intended use, Plaintiff could have avoided the injuries, harms, losses, and damages complained of herein.

213. As a direct and proximate result of Defendants' breach of express warranty, Plaintiff has sustained pecuniary loss and general damages in a sum exceeding the jurisdictional minimum of this Court.

214. As a proximate result of Defendants' breach of express warranty, as alleged herein, there was a measurable and significant interval of time during which Plaintiff suffered great mental anguish and other personal injury harms, losses, and damages.

215. As a proximate result of Defendants' breach of express warranty, as alleged herein, Plaintiff sustained a loss of income and/or loss of earning capacity and/or other damages.

216. Defendants are therefore liable for Plaintiff's damages arising from Defendants' breach of warranty.

SIXTH CAUSE OF ACTION

BREACH OF IMPLIED WARRANTY

(Against Merck Defendants, Organon and DOES 1-10, Inclusive)

217. Plaintiff incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein.

218. "Defendants" in this cause of action refers to Merck while it held the NDA and if it did so, to Organon during the period it held the NDA.

219. At all relevant times, Defendants engaged in the business of testing, developing, designing, manufacturing, marketing, selling, distributing, and promoting Singulair®, which was and is defective and unreasonably dangerous to consumers, including Plaintiff, thereby placing Singulair® into the stream of commerce.

220. Before the time Plaintiff purchased Singulair®, Defendants impliedly warranted to its consumers, including Plaintiff, that Singulair® was of merchantable quality and safe and fit for the use for which it was intended; specifically, as a medication.

221. Defendants failed to adequately disclose that Singulair® has dangerous propensities when used as intended and that use of Singulair® carries an increased risk of developing severe injuries, including Plaintiff's injuries.

222. Plaintiff was one of the intended beneficiaries of the implied warranties made by Defendants to purchasers of Singulair®.

223. Defendants expected Singulair® to reach, and Singulair® did in fact reach, consumers and users, including Plaintiff, without substantial change in the condition in which it was manufactured and sold by Defendants.

224. At all relevant times, Defendants were aware that consumers and users of their products, including Plaintiff, would use Singulair® as marketed by Defendants, which is to say that Plaintiffs were foreseeable users and purchasers of Singulair®.

225. Defendants intended that Singulair® be used in the manner in which Plaintiff, in fact, used it and which Defendants impliedly warranted to be of merchantable quality, safe, and fit for this use, even though Singulair® was not adequately tested or researched.

226. In reliance upon Defendants' implied warranty, Plaintiff purchased and used Singulair® as instructed and labeled and in the foreseeable manner intended, recommended, promoted, and marketed by Defendants.

227. Plaintiff could not have reasonably or adequately discovered or known of the risks of serious injury associated with Singulair®.

228. Defendants breached their implied warranty to Plaintiff in that Singulair® was not of merchantable quality, safe, or fit for its intended use, or adequately tested. Singulair® has dangerous propensities when used as intended and can cause serious injuries, including those injuries complained of herein.

229. The harm caused by Singulair® far outweighed its benefit, rendering the product more dangerous than an ordinary consumer or user would expect and more dangerous than alternative products.

230. As a direct and proximate result of Defendants' breach of implied warranty, Plaintiffs has sustained pecuniary loss and general damages in sums exceeding the jurisdictional minimum of this Court.

231. As a proximate result of the Defendants' breach of implied warranty, as alleged herein, there was a measurable and significant interval of time during which Plaintiffs suffered great mental anguish and other personal injury and damages.

232. As a proximate result of Defendants' breach of implied warranty, as alleged herein, Plaintiffs sustained a loss of income and/or loss of earning capacity and/or other damages.

233. Defendants are therefore liable for Plaintiff's damages arising from Defendants' breach of warranty.

RELIEF REQUESTED

WHEREFORE, PLAINTIFF prays for judgment against Defendants, and each of them, as follows:

1. Past and future general damages, the exact amount of which has yet to be ascertained, in an amount which will conform to proof at time of trial;

2. Past and future economic and special damages according to proof at the time of trial;

3. Loss of earnings and impaired earning capacity according to proof at the time of trial;

4. Medical expenses, past and future, according to proof at the time of trial;

5. Punitive or exemplary damages according to proof at the time of trial;

6. Attorney's fees, as allowable by law;

7. For costs of suit incurred herein;

8. For pre-judgment interest as provided by law; and

9. For such other and further relief as the Court may deem just and proper.

Respectfully submitted,

BOUCHER LLP

DATED: March 3, 2022

By: _____

SHEHNAZ M. BHUJWALA

WILENTZ, GOLDMAN & SPITZER
KEVIN P. RODDY

BECK LAW CENTER
KIMBERLY BECK

Attorneys for Plaintiff

DEMAND FOR JURY TRIAL

PLAINTIFF hereby demands a trial by jury as to all claims and issues in this action that are so triable.

Respectfully submitted,

BOUCHER LLP

DATED: March 3, 2022

By: _____
SHEHNAZ M. BHUJWALA

WILENTZ, GOLDMAN & SPITZER
KEVIN P. RODDY

BECK LAW CENTER
KIMBERLY BECK

Attorneys for Plaintiff

ATTORNEY OR PARTY WITHOUT ATTORNEY (Name, State Bar number, and address):
Shehnaz M. Bhujwala (SBN 223484)
Boucher LLP, 21600 Oxnard St., Suite 600, Woodland Hills, CA 91367
TELEPHONE NO.: (818) 340-5400 FAX NO. (Optional): (818) 340-5401
E-MAIL ADDRESS: bhujwala@boucher.la
ATTORNEY FOR (Name): Plaintiff Sherry Wallace

FOR COURT USE ONLY

ELECTRONICALLY FILED
Merced Superior Court
3/4/2022 10:08 AM
Amanda Toste
Clerk of the Superior Court
By: Tawn Saephanh, Deputy

SUPERIOR COURT OF CALIFORNIA, COUNTY OF Merced
STREET ADDRESS: 627 W 21st Streeet
MAILING ADDRESS:
CITY AND ZIP CODE: Merced, CA 95340
BRANCH NAME: Old Merced Courthouse

CASE NAME: Wallace v. Merck & Co., Inc., et al.

CIVIL CASE COVER SHEET

[X] **Unlimited** (Amount demanded exceeds $25,000)
[ ] **Limited** (Amount demanded is $25,000 or less)

Complex Case Designation

[ ] Counter [ ] Joinder

Filed with first appearance by defendant (Cal. Rules of Court, rule 3.402)

CASE NUMBER: 22CV-00737

JUDGE:
DEPT.:

Items 1–6 below must be completed (see instructions on page 2).

1. Check **one** box below for the case type that best describes this case:

Auto Tort
- [ ] Auto (22)
- [ ] Uninsured motorist (46)

Other PI/PD/WD (Personal Injury/Property Damage/Wrongful Death) Tort
- [ ] Asbestos (04)
- [X] Product liability (24)
- [ ] Medical malpractice (45)
- [ ] Other PI/PD/WD (23)

Non-PI/PD/WD (Other) Tort
- [ ] Business tort/unfair business practice (07)
- [ ] Civil rights (08)
- [ ] Defamation (13)
- [ ] Fraud (16)
- [ ] Intellectual property (19)
- [ ] Professional negligence (25)
- [ ] Other non-PI/PD/WD tort (35)

Employment
- [ ] Wrongful termination (36)
- [ ] Other employment (15)

Contract
- [ ] Breach of contract/warranty (06)
- [ ] Rule 3.740 collections (09)
- [ ] Other collections (09)
- [ ] Insurance coverage (18)
- [ ] Other contract (37)

Real Property
- [ ] Eminent domain/Inverse condemnation (14)
- [ ] Wrongful eviction (33)
- [ ] Other real property (26)

Unlawful Detainer
- [ ] Commercial (31)
- [ ] Residential (32)
- [ ] Drugs (38)

Judicial Review
- [ ] Asset forfeiture (05)
- [ ] Petition re: arbitration award (11)
- [ ] Writ of mandate (02)
- [ ] Other judicial review (39)

Provisionally Complex Civil Litigation (Cal. Rules of Court, rules 3.400–3.403)
- [ ] Antitrust/Trade regulation (03)
- [ ] Construction defect (10)
- [ ] Mass tort (40)
- [ ] Securities litigation (28)
- [ ] Environmental/Toxic tort (30)
- [ ] Insurance coverage claims arising from the above listed provisionally complex case types (41)

Enforcement of Judgment
- [ ] Enforcement of judgment (20)

Miscellaneous Civil Complaint
- [ ] RICO (27)
- [ ] Other complaint *(not specified above)* (42)

Miscellaneous Civil Petition
- [ ] Partnership and corporate governance (21)
- [ ] Other petition *(not specified above)* (43)

2. This case [X] is [ ] is not complex under rule 3.400 of the California Rules of Court. If the case is complex, mark the factors requiring exceptional judicial management:
   a. [X] Large number of separately represented parties
   b. [X] Extensive motion practice raising difficult or novel issues that will be time-consuming to resolve
   c. [X] Substantial amount of documentary evidence
   d. [X] Large number of witnesses
   e. [X] Coordination with related actions pending in one or more courts in other counties, states, or countries, or in a federal court
   f. [ ] Substantial postjudgment judicial supervision
3. Remedies sought *(check all that apply)*: a. [X] monetary b. [ ] nonmonetary; declaratory or injunctive relief c. [X] punitive
4. Number of causes of action *(specify)*: 6
5. This case [ ] is [X] is not a class action suit.
6. If there are any known related cases, file and serve a notice of related case. *(You may use form CM-015.)*

Date: March 3, 2022

Shehnaz M. Bhujwala
(TYPE OR PRINT NAME)

(SIGNATURE OF PARTY OR ATTORNEY FOR PARTY)

NOTICE

- Plaintiff must file this cover sheet with the first paper filed in the action or proceeding (except small claims cases or cases filed under the Probate Code, Family Code, or Welfare and Institutions Code). (Cal. Rules of Court, rule 3.220.) Failure to file may result in sanctions.
- File this cover sheet in addition to any cover sheet required by local court rule.
- If this case is complex under rule 3.400 et seq. of the California Rules of Court, you must serve a copy of this cover sheet on all other parties to the action or proceeding.
- Unless this is a collections case under rule 3.740 or a complex case, this cover sheet will be used for statistical purposes only.

INSTRUCTIONS ON HOW TO COMPLETE THE COVER SHEET

CM-010

To Plaintiffs and Others Filing First Papers. If you are filing a first paper (for example, a complaint) in a civil case, you **must** complete and file, along with your first paper, the Civil Case Cover Sheet contained on page 1. This information will be used to compile statistics about the types and numbers of cases filed. You must complete items 1 through 6 on the sheet. In item 1, you must check **one** box for the case type that best describes the case. If the case fits both a general and a more specific type of case listed in item 1, check the more specific one. If the case has multiple causes of action, check the box that best indicates the **primary** cause of action. To assist you in completing the sheet, examples of the cases that belong under each case type in item 1 are provided below. A cover sheet must be filed only with your initial paper. Failure to file a cover sheet with the first paper filed in a civil case may subject a party, its counsel, or both to sanctions under rules 2.30 and 3.220 of the California Rules of Court.

To Parties in Rule 3.740 Collections Cases. A "collections case" under rule 3.740 is defined as an action for recovery of money owed in a sum stated to be certain that is not more than $25,000, exclusive of interest and attorney's fees, arising from a transaction in which property, services, or money was acquired on credit. A collections case does not include an action seeking the following: (1) tort damages, (2) punitive damages, (3) recovery of real property, (4) recovery of personal property, or (5) a prejudgment writ of attachment. The identification of a case as a rule 3.740 collections case on this form means that it will be exempt from the general time-for-service requirements and case management rules, unless a defendant files a responsive pleading. A rule 3.740 collections case will be subject to the requirements for service and obtaining a judgment in rule 3.740.

To Parties in Complex Cases. In complex cases only, parties must also use the Civil Case Cover Sheet to designate whether the case is complex. If a plaintiff believes the case is complex under rule 3.400 of the California Rules of Court, this must be indicated by completing the appropriate boxes in items 1 and 2. If a plaintiff designates a case as complex, the cover sheet must be served with the complaint on all parties to the action. A defendant may file and serve no later than the time of its first appearance a joinder in the plaintiff's designation, a counter-designation that the case is not complex, or, if the plaintiff has made no designation, a designation that the case is complex.

CASE TYPES AND EXAMPLES

Auto Tort
- Auto (22)–Personal Injury/Property Damage/Wrongful Death
- Uninsured Motorist (46) *(if the case involves an uninsured motorist claim subject to arbitration, check this item instead of Auto)*

Other PI/PD/WD (Personal Injury/ Property Damage/Wrongful Death) Tort
- Asbestos (04)
  - Asbestos Property Damage
  - Asbestos Personal Injury/ Wrongful Death
- Product Liability *(not asbestos or toxic/environmental)* (24)
- Medical Malpractice (45)
  - Medical Malpractice–Physicians & Surgeons
- Other Professional Health Care Malpractice
- Other PI/PD/WD (23)
  - Premises Liability (e.g., slip and fall)
  - Intentional Bodily Injury/PD/WD (e.g., assault, vandalism)
  - Intentional Infliction of Emotional Distress
  - Negligent Infliction of Emotional Distress
  - Other PI/PD/WD

Non-PI/PD/WD (Other) Tort
- Business Tort/Unfair Business Practice (07)
- Civil Rights (e.g., discrimination, false arrest) *(not civil harassment)* (08)
- Defamation (e.g., slander, libel) (13)
- Fraud (16)
- Intellectual Property (19)
- Professional Negligence (25)
  - Legal Malpractice
  - Other Professional Malpractice *(not medical or legal)*
- Other Non-PI/PD/WD Tort (35)

Employment
- Wrongful Termination (36)
- Other Employment (15)

Contract
- Breach of Contract/Warranty (06)
  - Breach of Rental/Lease Contract *(not unlawful detainer or wrongful eviction)*
  - Contract/Warranty Breach–Seller Plaintiff *(not fraud or negligence)*
  - Negligent Breach of Contract/ Warranty
  - Other Breach of Contract/Warranty
- Collections (e.g., money owed, open book accounts) (09)
  - Collection Case–Seller Plaintiff
  - Other Promissory Note/Collections Case
- Insurance Coverage *(not provisionally complex)* (18)
  - Auto Subrogation
  - Other Coverage
- Other Contract (37)
  - Contractual Fraud
  - Other Contract Dispute

Real Property
- Eminent Domain/Inverse Condemnation (14)
- Wrongful Eviction (33)
- Other Real Property (e.g., quiet title) (26)
  - Writ of Possession of Real Property
  - Mortgage Foreclosure
  - Quiet Title
  - Other Real Property *(not eminent domain, landlord/tenant, or foreclosure)*

Unlawful Detainer
- Commercial (31)
- Residential (32)
- Drugs (38) *(if the case involves illegal drugs, check this item; otherwise, report as Commercial or Residential)*

Judicial Review
- Asset Forfeiture (05)
- Petition Re: Arbitration Award (11)
- Writ of Mandate (02)
  - Writ–Administrative Mandamus
  - Writ–Mandamus on Limited Court Case Matter
  - Writ–Other Limited Court Case Review
- Other Judicial Review (39)
  - Review of Health Officer Order
  - Notice of Appeal–Labor Commissioner Appeals

Provisionally Complex Civil Litigation (Cal. Rules of Court Rules 3.400–3.403)
- Antitrust/Trade Regulation (03)
- Construction Defect (10)
- Claims Involving Mass Tort (40)
- Securities Litigation (28)
- Environmental/Toxic Tort (30)
- Insurance Coverage Claims *(arising from provisionally complex case type listed above)* (41)

Enforcement of Judgment
- Enforcement of Judgment (20)
  - Abstract of Judgment (Out of County)
  - Confession of Judgment *(non-domestic relations)*
  - Sister State Judgment
  - Administrative Agency Award *(not unpaid taxes)*
  - Petition/Certification of Entry of Judgment on Unpaid Taxes
  - Other Enforcement of Judgment Case

Miscellaneous Civil Complaint
- RICO (27)
- Other Complaint *(not specified above)* (42)
  - Declaratory Relief Only
  - Injunctive Relief Only *(non-harassment)*
  - Mechanics Lien
  - Other Commercial Complaint Case *(non-tort/non-complex)*
  - Other Civil Complaint *(non-tort/non-complex)*

Miscellaneous Civil Petition
- Partnership and Corporate Governance (21)
- Other Petition *(not specified above)* (43)
  - Civil Harassment
  - Workplace Violence
  - Elder/Dependent Adult Abuse
  - Election Contest
  - Petition for Name Change
  - Petition for Relief From Late Claim
  - Other Civil Petition

For your protection and privacy, please press the Clear This Form button after you have printed the form.

Print this form | Save this form | Clear this form

EXHIBIT 2

STATE OF NEW JERSEY
DEPARTMENT OF THE TREASURY
DIVISION OF REVENUE AND ENTERPRISE SERVICES
SHORT FORM STANDING

MERCK & CO., INC.
7954610000

I, the Treasurer of the State of New Jersey, do hereby certify that the above-named New Jersey Domestic For-Profit Corporation was registered by this office on July 28, 1970.

As of the date of this certificate, said business continues as an active business in good standing in the State of New Jersey, and its Annual Reports are current.

I further certify that the registered agent and office are:

C T CORPORATION SYSTEM
820 BEAR TAVERN ROAD
WEST TRENTON, NJ 08628

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed my Official Seal at Trenton, this 7th day of March, 2022

Elizabeth Maher Muoio
State Treasurer

Certificate Number : 6129269226

Verify this certificate online at

https://www1.state.nj.us/TYTR_StandingCert/JSP/Verify_Cert.jsp

EXHIBIT 3

Status Report For:	MERCK & CO., INC.
Report Date:	3/7/2022
Confirmation Number:	220662587838

IDENTIFICATION NUMBER, ENTITY TYPE AND STATUS INFORMATION

Business ID Number:	7954610000
Business Type:	DOMESTIC PROFIT CORPORATION
Status:	ACTIVE
Original Filing Date:	07/28/1970
Stock Amount:	6520000000
Home Jurisdiction:	NJ
Status Change Date:	11-02-2009

REVOCATION/SUSPENSION INFORMATION

DOR Suspension Start Date:	N/A
DOR Suspension End Date:	N/A
Tax Suspension Start Date:	N/A
Tax Suspension End Date:	N/A

ANNUAL REPORT INFORMATION

Annual Report Month:	JULY
Last Annual Report Filed:	07/21/2021
Year:	2021

AGENT/SERVICE OF PROCESS (SOP)INFORMATION

Agent:	C T CORPORATION SYSTEM
Agent/SOP Address:	820 BEAR TAVERN ROAD ,WEST TRENTON,NJ,08628
Address Status:	DELIVERABLE
Main Business Address:	2000 GALLOPING HILL ROAD, KENILWORTH, NJ, 07033 1310
Principal Business Address:	2000 GALLOPING HILL ROAD,KENILWORTH,NJ,07033 1310

ASSOCIATED NAMES

Associated Name:	SCHERING-PLOUGH CORPORATION
Type:	PV

PRINCIPALS

Following are the most recently reported officers/directors (corporations), managers/members/managing members (LLCs), general partners (LPs), trustees/officers (non-profits).

Title:	PRESIDENT
Name:	KARACHUN,RITA
Address:	2000 GALLOPING HILL ROAD, KENILWORTH, , , US
Title:	SECRETARY
Name:	FILDERMAN,JON
Address:	2000 GALLOPING HILL ROAD, KENILWORTH, , , US
Title:	TREASURER
Name:	LITCHFIELD,CAROLINE
Address:	2000 GALLOPING HILL ROAD, KENILWORTH, , , US
Title:	OTHER
Name:	Grez,Kelly E
Address:	2000 GALLOPING HILL ROAD, KENILWORTH, , , US

FILING HISTORY -- CORPORATIONS, LIMITED LIABILITY COMPANIES, LIMITED PARTNERSHIPS AND LIMITED LIABILITY PARTNERSHIPS

To order copies of any of the filings below, return to the service page, https://www.njportal.com/DOR/businessrecords/Default.aspx and follow the instructions for obtaining copies. Please note that trade names are filed initially with the County Clerk(s) and are not available through this service. Contact the Division for instructions on how to order Trade Mark documents.

Charter Documents for Corporations, LLCs, LPs and LLPs

Original Filing (Certificate)Date:	1970

Changes and Amendments to the Original Certificate:

Filing Type	Year Filed
CHANGE OF REGISTERED OFFICE	1984
CHANGE OF REGISTERED OFFICE	1984
CHANGE OF REGISTERED AGENT	2000
CHANGE OF REGISTERED AGENT	2001
CHANGE OF REGISTERED AGENT	2004
CHANGE OF REGISTERED AGENT	1994
CORRECTION	2004
MERGER	2009

MERGER	1987
MERGER	1990
RESTATED	2004
RESTATED	2007
RESTATED	2006
RESTATED	2007
RESTATED	2007
RESTATED WITH NAME CHANGE	2009
CHANGE OF AGENT AND OFFICE	2000
CHANGE OF AGENT AND OFFICE	2008
CHANGE OF AGENT AND OFFICE	1996
AMENDMENT	2004
AMENDMENT	2007
AMENDMENT	2007
AMENDMENT	2021
AMENDMENT	1971
AMENDMENT	1971
AMENDMENT	1973
AMENDMENT	1975
AMENDMENT	1979
AMENDMENT	1979
AMENDMENT	1984
AMENDMENT	1984
AMENDMENT	1985
AMENDMENT	1987
AMENDMENT	1989
AMENDMENT	1995
AMENDMENT	1997
AMENDMENT	1998
AMENDMENT	1997
Annual Report Filing with address change	2015
Annual Report filing with officer/member change	2015
Annual Report filing with officer/member change	2016
Annual Report filing with officer/member change	2017
Annual Report filing with officer/member change	2018
Annual Report filing with officer/member change	2019
Annual Report filing with officer/member change	2020
Annual Report filing with officer/member change	2021

Note:
Copies of some of the charter documents above, particularly those filed before June 1988 and recently filed documents (filed less than 20 work days from the current date), may not be available for online download.

- For older filings, contact the Division for instructions on how to order.
- For recent filings, allow 20 work days from the estimated filing date, revisit the service center at https://www.njportal.com/DOR/businessrecords/Default.aspx periodically, search for the business again and build a current list of its filings. Repeat this procedure until the document shows on the list of documents available for download.

The Division cannot provide information on filing requests that are in process. Only officially filed documents are available for download.

EXHIBIT 4

Secretary of State
Statement of Information
(California Stock, Agricultural Cooperative and Foreign Corporations)

SI-550

111

IMPORTANT — Read instructions **before completing this form. Fees (Filing plus Disclosure) – $25.00;**

Copy Fees – First page $1.00; each attachment page $0.50; Certification Fee - $5.00 plus copy fees

FILED
Secretary of State
State of California
DEC 20 2021

This Space For Office Use Only

1. Corporation Name (Enter the **exact** name of the corporation as it is recorded with the California Secretary of State. Note: If you registered in California using an assumed name, see instructions.)

Merck Sharp & Dohme Corp.

2. 7-Digit Secretary of State Entity Number

C0200917

3. Business Addresses

	City (no abbreviations)	State	Zip Code
a. Street Address of Principal Executive Office - Do not list a P.O. Box 2000 Galloping Hill Road	Kenilworth	NJ	07033
b. Mailing Address of Corporation, **if different than item 3a**	City (no abbreviations)	State	Zip Code
c. Street Address of Principal **California** Office, if any and if different than Item 3a - Do not list a P.O. Box	City (no abbreviations)	State CA	Zip Code

4. Officers The Corporation is required to list all three of the officers set forth below. An additional title for the Chief Executive Officer and Chief Financial Officer may be added; however, the preprinted titles on this form must not be altered.

	First Name	Middle Name	Last Name	Suffix
a. **Chief Executive Officer/**	Rita		Karachun	
Address: 2000 Galloping Hill Road			City: Kenilworth	State: NJ, Zip Code: 07033
b. **Secretary**	Kelly		Grez	
Address: 2000 Galloping Hill Road			City: Kenilworth	State: NJ, Zip Code: 07033
c. **Chief Financial Officer/**	Jon		Filderman	
Address: 2000 Galloping Hill Road			City: Kenilworth	State: NJ, Zip Code: 07033

5. Director(s) California Stock and Agricultural Cooperative Corporations ONLY: **Item 5a:** At least one name **and** address must be listed. If the Corporation has additional directors, enter the name(s) and addresses on Form SI-550A (see instructions).

	Middle Name	Last Name	Suffix
a. First Name: Rita		Karachun	
Address: 2000 Galloping Hill Road		City: Kenilworth	State: NJ, Zip Code: 07033
b. Number of Vacancies on the Board of Directors, if any			

6. Service of Process (Must provide either Individual **OR** Corporation.)

INDIVIDUAL – Complete Items 6a and 6b only. Must include agent's full name and California street address.

	Middle Name	Last Name	Suffix
a. California Agent's First Name (if agent is **not** a corporation)			
b. Street Address (if agent is **not** a corporation) - **Do not enter a P.O. Box**	City (no abbreviations)	State: CA	Zip Code

CORPORATION – Complete Item 6c only. Only include the name of the registered agent Corporation.

c. California Registered Corporate Agent's Name (if agent is a corporation) – Do not complete Item 6a or 6b
C T Corporation C0168406

7. Type of Business

Describe the type of business or services of the Corporation
Pharmaceutical manufacturing

8. The Information contained herein, including in any attachments, is true and correct.

12/13/2021	Brian DiMaria	Authorized Representative	
Date	Type or Print Name of Person Completing the Form	Title	Signature

Clear Form Print Form

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Attachment to Statement of Information
(California Stock and Agricultural Cooperative Corporations)

SI-550A Attachment

A. Corporation Name

Merck Sharp & Dohme Corp.

B. 7-Digit Secretary of State Entity Number

C0200917

This Space For Office Use Only

C. List of Additional Director(s) – If the corporation has more than one director, enter the additional directors' names and addresses.

	Middle Name	Last Name	Suffix
5b. First Name: Aaron		Rosenberg	
Address: 2000 Galloping Hill Road	City (no abbreviations): Kenilworth	State: NJ	Zip Code: 07033
5c. First Name: Timothy		Dillane	
Address: 2000 Galloping Hill Road	City (no abbreviations): Kenilworth	State: NJ	Zip Code: 07033
5d. First Name: Karen		Ettelman	
Address: 2000 Galloping Hill Road	City (no abbreviations): Kenilworth	State: NJ	Zip Code: 07033
5e. First Name: Juanita		Lee	
Address: 2000 Galloping Hill Road	City (no abbreviations): Kenilworth	State: NJ	Zip Code: 07033
5f. First Name: Jerome		Mychalowych	
Address: 2000 Galloping Hill Road	City (no abbreviations): Kenilworth	State: NJ	Zip Code: 07033
5g. First Name: Michael		Schwartz	
Address: 2000 Galloping Hill Road	City (no abbreviations): Kenilworth	State: NJ	Zip Code: 07033
5h. First Name:			
Address:	City (no abbreviations):	State:	Zip Code:
5i. First Name:			
Address:	City (no abbreviations):	State:	Zip Code:
5j. First Name:			
Address:	City (no abbreviations):	State:	Zip Code:

Clear Form Print Form

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EXHIBIT 5

STATE OF NEW JERSEY
DEPARTMENT OF THE TREASURY
DIVISION OF REVENUE AND ENTERPRISE SERVICES
SHORT FORM STANDING

MERCK SHARP & DOHME LLC
0600468333

I, the Treasurer of the State of New Jersey, do hereby certify that the above-named New Jersey Domestic Limited Liability Company was registered by this office on June 29, 2020.

As of the date of this certificate, said business continues as an active business in good standing in the State of New Jersey, and its Annual Reports are current.

I further certify that the registered agent and office are:

C T CORPORATION SYSTEM
820 BEAR TAVERN ROAD
WEST TRENTON, NJ 08628

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed my Official Seal at Trenton, this 19th day of May, 2022

Elizabeth Maher Muoio
State Treasurer

Certificate Number : 6132076627

Verify this certificate online at

https://www1.state.nj.us/TYTR_StandingCert/JSP/Verify_Cert.jsp

EXHIBIT 6

Status Report For:	MERCK SHARP & DOHME LLC
Report Date:	5/19/2022
Confirmation Number:	221392662366

IDENTIFICATION NUMBER, ENTITY TYPE AND STATUS INFORMATION

Business ID Number:	0600468333
Business Type:	DOMESTIC LIMITED LIABILITY COMPANY
Status:	ACTIVE
Original Filing Date:	06/29/2020
Stock Amount:	N/A
Home Jurisdiction:	NJ
Status Change Date:	04-12-2022

REVOCATION/SUSPENSION INFORMATION

DOR Suspension Start Date:	N/A
DOR Suspension End Date:	N/A
Tax Suspension Start Date:	N/A
Tax Suspension End Date:	N/A

ANNUAL REPORT INFORMATION

Annual Report Month:	JUNE
Last Annual Report Filed:	05/24/2021
Year:	2021

AGENT/SERVICE OF PROCESS (SOP)INFORMATION

Agent:	C T CORPORATION SYSTEM
Agent/SOP Address:	820 BEAR TAVERN ROAD ,WEST TRENTON,NJ,08628
Address Status:	DELIVERABLE
Main Business Address:	126 EAST LINCOLN AVE., PO BOX 2000, RAHWAY, NJ, 07065
Principal Business Address:	2000 Galloping Hill Rd,Kenilworth,NJ,07033

ASSOCIATED NAMES

Associated Name:	N/A
Type:	N/A

PRINCIPALS

Following are the most recently reported officers/directors (corporations), managers/members/managing members (LLCs), general partners (LPs), trustees/officers (non-profits).

Title:	PRESIDENT
Name:	Karachun,Rita
Address:	2000 Galloping Hill Rd, Kenilworth, , , US
Title:	VICE PRESIDENT
Name:	Filderman,John
Address:	2000 Galloping Hill Rd, Kenilworth, , , US
Title:	TREASURER
Name:	Litchfield,Caroline
Address:	2000 Galloping Hill Rd, Kenilworth, , , US

FILING HISTORY -- CORPORATIONS, LIMITED LIABILITY COMPANIES, LIMITED PARTNERSHIPS AND LIMITED LIABILITY PARTNERSHIPS

To order copies of any of the filings below, return to the service page, https://www.njportal.com/DOR/businessrecords/Default.aspx and follow the instructions for obtaining copies. Please note that trade names are filed initially with the County Clerk(s) and are not available through this service. Contact the Division for instructions on how to order Trade Mark documents.

Charter Documents for Corporations, LLCs, LPs and LLPs

Original Filing (Certificate)Date:	2020

Changes and Amendments to the Original Certificate:

Filing Type	Year Filed
CORRECTION	2022
MERGER	2022
Annual Report Filing with address change	2021
Annual Report filing with officer/member change	2021

Note:
Copies of some of the charter documents above, particularly those filed before June 1988 and recently filed documents (filed less than 20 work days from the current date), may not be available for online download.

- For older filings, contact the Division for instructions on how to order.
- For recent filings, allow 20 work days from the estimated filing date, revisit the service center at https://www.njportal.com/DOR/businessrecords/Default.aspx

periodically, search for the business again and build a current list of its filings. Repeat this procedure until the document shows on the list of documents available for download.

The Division cannot provide information on filing requests that are in process. Only officially filed documents are available for download.

EXHIBIT 7

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "ORGANON & CO." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE EIGHTH DAY OF MARCH, A.D. 2022.

Jeffrey W. Bullock, Secretary of State

7834229 8300

SR# 20220910198

Authentication: 202857472

Date: 03-08-22

You may verify this certificate online at corp.delaware.gov/authver.shtml

EXHIBIT 8

STATE OF NEW JERSEY
DEPARTMENT OF THE TREASURY
DIVISION OF REVENUE AND ENTERPRISE SERVICES
SHORT FORM STANDING

ORGANON & CO.
0101057626

I, the Treasurer of the State of New Jersey, do hereby certify that the above-named Delaware Foreign For-Profit Corporation was registered by this office on February 23, 2021.

As of the date of this certificate, said business continues as an active business in good standing in the State of New Jersey, and its Annual Reports are current.

I further certify that the registered agent and office are:

C T CORPORATION SYSTEM
820 BEAR TAVERN ROAD
WEST TRENTON, NJ 08628

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed my Official Seal at Trenton, this 7th day of March, 2022

Elizabeth Maher Muoio
State Treasurer

Certificate Number : 6129269156

Verify this certificate online at

https://www1.state.nj.us/TYTR_StandingCert/JSP/Verify_Cert.jsp

EXHIBIT 9

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "ORGANON LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE EIGHTH DAY OF MARCH, A.D. 2022.

Jeffrey W. Bullock, Secretary of State

7803284 8300

SR# 20220910323

Authentication: 202858233

Date: 03-08-22

You may verify this certificate online at corp.delaware.gov/authver.shtml

EXHIBIT 10

STATE OF NEW JERSEY
DEPARTMENT OF THE TREASURY
DIVISION OF REVENUE AND ENTERPRISE SERVICES
SHORT FORM STANDING

ORGANON LLC
0600467987

I, the Treasurer of the State of New Jersey, do hereby certify that the above-named Delaware Foreign Limited Liability Company was registered by this office on May 13, 2020.

As of the date of this certificate, said business continues as an active business in good standing in the State of New Jersey, and its Annual Reports are current.

I further certify that the registered agent and office are:

C T CORPORATION SYSTEM
820 BEAR TAVERN ROAD
WEST TRENTON, NJ 08628

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed my Official Seal at Trenton, this 7th day of March, 2022

Elizabeth Maher Muoio
State Treasurer

Certificate Number : 6129269364

Verify this certificate online at

https://www1.state.nj.us/TYTR_StandingCert/JSP/Verify_Cert.jsp

EXHIBIT 11

Secretary of State
Statement of Information
(Limited Liability Company)

LLC-12

21C55432

FILED

In the office of the Secretary of State
of the State of California

MAY 17, 2021

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IMPORTANT — Read instructions **before completing this form.**

Filing Fee – $20.00

Copy Fees – First page $1.00; each attachment page $0.50;
Certification Fee - $5.00 plus copy fees

1. Limited Liability Company Name (Enter the exact name of the LLC. If you registered in California using an alternate name, see instructions.)

ORGANON LLC

2. 12-Digit Secretary of State File Number	3. State, Foreign Country or Place of Organization (only if formed outside of California)
202017610765	DELAWARE

4. Business Addresses

	City (no abbreviations)	State	Zip Code
a. Street Address of Principal Office - Do not list a P.O. Box 30 Hudson Street, 33rd Floor	Jersey City	NJ	07302
b. Mailing Address of LLC, **if different than item 4a** 30 Hudson Street, 33rd Floor	Jersey City	NJ	07302
c. Street Address of **California** Office, if Item 4a is not in California - Do not list a P.O. Box		**CA**	

5. Manager(s) or Member(s)

If no **managers** have been appointed or elected, provide the name and address of each **member**. At least one name **and** address must be listed. If the manager/member is an individual, complete Items 5a and 5c (leave Item 5b blank). If the manager/member is an entity, complete Items 5b and 5c (leave Item 5a blank). Note: The LLC cannot serve as its own manager or member. If the LLC has additional managers/members, enter the name(s) and addresses on Form LLC-12A (see instructions).

a. First Name, if an individual - Do not complete Item 5b	Middle Name	Last Name	Suffix

b. Entity Name - Do not complete Item 5a
Organon & Co.

c. Address	City (no abbreviations)	State	Zip Code
30 Hudson Street, 33rd Floor	Jersey City	NJ	07302

6. Service of Process (Must provide either Individual **OR** Corporation.)

INDIVIDUAL – Complete Items 6a and 6b only. Must include agent's full name and California street address.

a. California Agent's First Name (if agent is **not** a corporation)	Middle Name	Last Name	Suffix

b. Street Address (if agent is **not** a corporation) - **Do not enter a P.O. Box**	City (no abbreviations)	State	Zip Code
		CA	

CORPORATION – Complete Item 6c only. Only include the name of the registered agent Corporation.

c. California Registered Corporate Agent's Name (if agent is a corporation) – Do not complete Item 6a or 6b
C T CORPORATION SYSTEM (C0168406)

7. Type of Business

a. Describe the type of business or services of the Limited Liability Company
wholesale drug and manufacturing company

8. Chief Executive Officer, if elected or appointed

a. First Name	Middle Name	Last Name	Suffix

b. Address	City (no abbreviations)	State	Zip Code

9. The Information contained herein, including any attachments, is true and correct.

05/17/2021	Faye C Brown	Assistant Secretary	
Date	Type or Print Name of Person Completing the Form	Title	Signature

Return Address (Optional) (For communication from the Secretary of State related to this document, or if purchasing a copy of the filed document enter the name of a person or company and the mailing address. This information will become public when filed. SEE INSTRUCTIONS BEFORE COMPLETING.)

Name:

Company:

Address:

City/State/Zip: